

MEDWATCH

AL PRODUCTS REPORTING PROGRAM

Approved by the FDA on 09/24/1999 .						
Mfr report #	EQ6522130MAY2000					
uF/Dist repor	-					
	FDA Use Only					

A. Patient i	-9-00-01* ntormatic	e meg 200 grander	olegen (mgggatt) gramatika	Page 1 o			<u> </u>	FDA Use O
Patient ident fier	2. Age at time	711 1 6 (8)	3. Sex	4. Weight	C. Suspec	et medicatio	n(s)	
	of event:	7Yr	female	215 lbs	1. Name (give labeled #1 LODINE (ET	strength & mfr/abeler, if 'ODOLAC, Capsul	known)	
	Date of			or	11	CYLIC ACID (AC		
n confidence	Birth:		X male	kgs		(c	ont'd)	C AC10. }
B. Adverse					2. Dose frequency & #1 500 mg 2x		3. The apy data	is (if unknown, give duration)
1. X Adverse e		Prod	uct problem (e.g., de	fects/malfunctions)	Urai		*1 00/00/3	1999 to UNK
Outcomes attributed (check all that apply)	to adverse event)	-	disability		#2 Dose not s Oral	pecified,	#2 00/00/3	1999 to UNK
death	·	<u> </u>	congenital anomaly		4. Diagnosis for use (in	udication)	<u></u>	
life -threatening	ic/day/yr)		required intervention permanent impairme	to prevent nt/damage	*1 Arthritis		str	Event abated after use opped or dose reduced
X hospitalization-in X recovered	tial or prolonged		other:		# 2 UNK		*	1 yes no X app
Date of average		T 4 200]		#:	2 yes no X does
(mo/day/yr)	0/00/1999		of this report o/day/yr)	03/28/2001	6. Lot # (if known)	7. Exp date (if know	νn)	ш ш ст арр
Describe event or pro		on 26-M	AY-2000 from	a physici		#1	8. i re:i	Event reappeared after ntroduction
ia Merck & Co	Inc. and	on 12-0	JUN-2000 from	a	# 2	# 2		1 yes X no doesa
ig:stered nur tite male bat	se via Cova ient. The	ince rega	arding a 67-ye	ear-old	9 NOC 4 tor prod	problems only (if known)		
oclude Arthri	tis NOS. 7	dditiona	al medical his	tory was			1	yes 10 X apply
ot provided.	- Therapy wi	th LODIN	NE CAPSULE (et in 1990 (ther	odolar	10. Concomitant medic: UNK	al products and therapy d	lates (exclude treat	ment of event)
ct specified)	. The dose	regimer	included: ty	ro. 500mc	G. All mar	ufacturas		
ises, every d	ay. Additi	onal sus	spect medicati NAPROXEN SON	on	Contact office – name		eren eren eren eren eren eren eren eren	2. Phone number
stient experi	enced stoma	ch bleed	ding (Gastroic	restina"	WYETH LABS (R. 240 N Radnor-	i) Thuster		6109024647
semoirhage NO CETYLSALICYLI	S) while ta C ACID (Dru	king LOE g intera	OINE CAPSULE a	nd Va	St. Davids, P	X 19087		3. Report source.
bsequently h	ospitalized	for two	days and nin	hts The	Jill Robinson			(check all that apply)
tient "was f: ntinued LODI	ine' at the VE CAPSULE	time of therapy	discharge an	d TC ACID	}			foreign
s discontinue	ed). In fo	llow-up	information r	eceived on				literature
-JUN-2000, th DINE CAPSULE	ne nurse in (etodolac	dicated	the patient w	as taking	11			Consumer
		nt'd)	concomica.ici	y with	Date received by man	ufacturer 5.		X health professional
Rejevant tests/faborato	ry data, including d	ates			(mo/day/yr)	1(A)	NDA 18-922	user facility
one Provided.					05/26/2	[""	D# A#	company representative
					6. If IND, protocol #	pre-		distributor
						orc		other;
					7. Type of report	produ		<u> </u>
ther relevant history, i	notaixsera gribulan	medica cont	#tions		5-day 15-d		verse event term(s) prointestin	al haemorrhage
aliergies, race, preg CURREN'I COND		alcohol use,	hepatic/renal dysfunction	on e.c.)	10-day X perio	nos Nos		_
hritis NOS					X initial follow	v-up #Drug	interaction	on NGS
					9. Mfr. report number			
				1	HQ6622130MA	Y2000		
				j				
					E. Initial rep	orter	e ge Teknologistisk kol	<u> </u>
					1. Name & address Hostelley, Line	da S Dr	phone ¥	610-397-2416
					PO Box 4	nc.		
					West Point, PA	19486, US		
	Submission of	a report does	got constitute an admi	ssion that	2. Health professional?	3. Occupation	4 Init	nal reporter also
rm 3500A (facsimile)	medical perso caused or con	mier, user raci	UTV. DISTRIBLIOF maputa	oturer or product	🔀 yes 🗌 no	Physiciai	r r—	ent report to FDA
				27	<u> </u>		L	yes Mark

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Wf report # HQ6622130MAY2000

UF/D st report a

FDA Use Only

e 2 of 2 Box B.5 - Describe event or problem (Continuation)

Aleve (NAPROXEN SODIUM) Additional information has been requested.

Box C - Suspect medication(s) (Continuation)

- 1. Name (give labeled strength & mfr/labeler, if known)
- # 3.1 NAPROXEN SODIUM (NAPROXEN SODIUM,)
- 2. Dose, frequency & route used
- # 3.1 1 Tablet 2x per 1 Day, Oral
- 3. Therapy dates (if unknown, give duration)
 - # 3.1 05/31/1998 to 05/31/1999
- 4. Diagnosis for use (indication)
 - # 3.1 Arthritis NOS
- 5. Event abated after use stopped or dose reduced
- # 3.1 DOESN'T APPLY
- 6. Lot # (if known)
- # 3.1
- 7. Exp date (if known)
- 3 Event reappeared after reintroduction
- # 3.1 DOESN'T APPLY



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ĺ	UF	Dist	re	öart	*

Merck Facsimile of Approved by FDA	
Mfr report #	WAES C1022014

Page 1 Mil

Mfr report #	WAES C1022014	İ
UF/Dist report #		•
	FDA Jse Oni	1

A Detient information			C. Su	spect n	nedicat	ion(s)			
A. Patient information Patient identifier 2. Age at time	3. Sex	4. Weight	1. Name (give	VIOXX Un	oth & mir/labele	er, if knows)			
of event:	Fernale			VIOAN UII				· 	
Same		205 pounds	*2		(Caption)	d an Additio	nal Pane)		
n confidence Birth:	X Male		3 Dans 4000	uency & route	(Continued	3. Therapy of	ates (fromvto	f unknown, giv	e duration:
B. Adverse event or produ	uct problem		4	ng/DAILY/F		I .	11/27′00 -		
Adverse event and/or	Product problem (e.g., de	efects/mailunctions)		11907112771		-			
2. Outcomes attributed to adverse event			# 2			# 2			
(cneck all that apply)	X disability		4. Diagnosis	for use (indica	(non)		5.Event abai reduced.	ed after use stop	oed 1.7 dose
	congenital anor	maly	#1 pain	, osteoarthr	itis		ves	no N/A	unk
(mo/day/yt)	required interve	ention to prevent	12				*: <u>X</u>		. ''
X life-threatening		airment/damage	6. Lot # (if kr	nown)	7. Exp date	(if known)	# 2		
X hospitalization-initial or prolonged	X other: importa	int medical	# 1		#1		3. Event rea	opea ed after rei	ntroc action
3. Date of avairs 01/31/01 1	te of this report	04/04/01	*2		#2		/es	no N/A	Jifix
morday/vr*			9. NDC # - 1	or product prob	iems only (il kr	iown)			
his is in follow-up to report((s) previously	submitted on		Unk	nown		+2		
,1:01: 3:7/01							-	2001 21 07:2011	
nformation has been received f	from a physicia	n, medical	10. Concor	itant medical p	roducts and the	erapy dates (e	xciuded freatr Unik -U		
ecords, and a completed questive or old white male with hypert	rongion labbrox	THACETA	DARVOC	ET-N			Unk -'		
no C disharac mailifile	e nvoercensive	COLOMALY			(Continue	ed on Addit	tiona Page	a)	
ascular disease, epigastric pane pack a day), occasional alo	cono consumpli	.01.	G A	ll manu	facture				
me pack a day), octasional arc hypercholesterolemia, a penicil http://coagulation (1991), spina				office - name/a				2 Phone Nur	nce
i an disorder depression (19/	ZI. Condescive	.:Ed	1 1					(610)397	7-2416
failure with orthopnea and show exertion, and a history of a "	riness of Dreat	TI DII	1 1		Health D	DIVISION		3. Report source	e
-fraction manning ulgar disease	p (19/2) "OLL d	ing on ,	Merc	k & Co.,	Inc.			(check all tha	at apply)
'active" ulcer (1978), headach	e, dizziness. 9 996). adenoideo	coronaly	P.O.	Box 4				lareign	
	CTV [YY: LWIL	JE 14. 477777	West	Point, P	A 19486-	0004		SILIDY	
low back pain (1983), appended myocardial infarction (1987, 1	fomv (1937), au	Tale interior						Interatu	re
1993., ankle sprain (December	2000), cardiac	c	ATTI	v: Worldv	vide Prod	luct Safe	ety	consun	ner
				ceived by man	udacauer	5.		X health protes	sior at
(Continued on Add	ditional Page)	TO FACE	4 Date re		3/28/01	(A)NDA # 2	21042	user ta	
6 Relevant tests/laboratory data, including dates		MIEK LON OF	1			IND # _		X compar	
Refer to Additional Page	//9	· · · · · · · · · · · · · · · · · · ·	6 HIND.	HOTOCOH #		PLA *		distribu	itor
	\mathscr{U}	MECO	Type of	enout		pre-1938 OTC	yes	other	
		APR 1 1 2001	5-day	157	y	product	yes		
	$\mathcal{H}_{\mathcal{F}}$	ricy D	10-02	=		9. Mfr. ret	port number	<u></u>	
	1:5		Initial	X Follow				S 01022014	
	N.	KOV OND PERS		event termis;		J			
	`		HEMOR	RHAGIC D	UODENAL :	JLCER; GA	ASTRITIS		
							:	\2 1	
			-			ሊያዩ	11	, s.a., .a.	
7 Other relevant history, including preexisting medic reigi, allergies, face pregnancy, smoking and alcoh	al conditions 101 use, hepatic/renal dysfu	unction, etc				54,			
wrotely HISTORY: acute anterly	or myocardial :	infarolion:	E. In	itial re	porter				
nouse inferior myodardia' inf	arction: aceno:	idediamy:		address & ono					
anglopiasty: appendectomy; ar	coronary arter	sis, cardiac y stent					•		
n acement inner respiratory	intection; tran	nsurethra.							
prostatectomy: tonsillectomy;	pseudoaneurys	m:	4						
.0	Additional Page								
	Additional Page)		2 Health	protessional?	3 Occ	upation		reporter also	
Submission of a report does medical personnel, user facil	not constitute an ad	unission inat utacturer or	X YE	s 🔲 N	0	M.D.	ye	_	X

product caused or contributed to the event.

WAES 01022014

B. Adverse event or product problem

5. Describe event or problem

catheterization (1991, 1996), right femoral arterial thrombosis (1991), pseudoaneurysm (1991; catheterization (1991, 1996), right remoral afterial thrombosis (1991), pseudoaneurysm (1991) transurethral prostatectomy (1985), nephrolithiasis (1967, 1983), pertussis (age 9), chest pain (1972), and acute anterior myocardial infarction (1991). The patient's family history included: father with 'heart trouble' who died in his late 70's after a colon resection for diverticilities mother who had a pacemaker and who died at age 70 of diabetes and nigh blood pressure, grandfather mother who had a pacemaker and who died at age 70 or diabetes and high blood pressure, grandfather who died at age 65 with kidney disease, and grandmother who died of diabetes. On 27-NOV-2030 the patient was placed on therapy with rofecoxib, tablet, 50 mg daily for three days, then 25 mg, once daily, for the treatment of back pain sometimes radiating to the legs and osteoarthritis. Concomitant therapy included warfarin sodium (COUMADIN), 7.5 mg daily except for Tuesdays, as Concomitant therapy included warfarin sodium (COUMADIN), 7.5 mg daily except for Tuesdays, as anti-coagulant therapy and "baby" aspirin, 81 mg, one daily, as cardiovascular disorder prophylaxis. Other concomitant therapy included amlodipine besylate (NORVASC), metformin HCl (GLUCOPHAGE), pioglitazone hydrochloride (ACTOS), ferrous sulfate (SLOW FE), pravastatin Na (PRAVACHOL), acetaminophen (+) propoxyphene napsylate (DARVOCET-N) and furosemide (LASIX). Prior therapy included ramitidine hydrochloride (Zantac) for treatment of peptic ulcer disease. In January 2001 the patient developed flu-like symptoms with mild nausea, headaches, myalgias, and anorexia. On 31-JAN-2001 the patient felt better and ate a breakfast consisting of pancakes and sausage. At approximately 1:00 pm on 31-JAN-2001 the patient had an episode of massive emesis which ne'd attributed to bad sausage. Two hours later the patient had a second episode of emesis. That day, the patient went to the emergency room. Current medications on admission included amlodiping pesylate, warfarin sodium, metformin HCl. pravastatin Na. aspirin, and acetaminophen → propoxypn≥ne napsylate. The patient complained that he had some lightheadedness, worsening orthopnea and snortness of breath on exertion, and a mild nonproductive cough. There was no chest pain or palpitations. The patient noted his history of ongoing epigastric pain on and off, and reported that on that day it was located to the epigastrium and was non radiating, not associated with emesis. The patient denied hematemesis, hematochezia, melena, urinary hesitancy, urinary urgency urinary burning or dysuria. Upon physical examination blood pressure was 148/59, pulse was 111. respirations were 16, temperature was 98.9 F, and pulse oximetry 94% on room air. Neck demonstrated positive jugular venous distention. Lungs showed bibasilar crackles. Heart showed mild tachycardia without murmur, and peripheral pulses were 2-. Abdomen was soft with bowel sounds in all four quadrants. There was mild epigastric tenderness with mild guarding, no rebound. Mild left lower quadrant tenderness without guarding or repound, and no masses were noted. Rectal exam demonstrated good tone, prostate was not inflamed, stool was fecal occult blood positive. On 31-JAN-2001 a chest x-ray revealed mild congestive heart failure with fluid in the costophrenic gutter, as well as mild x-ray revealed mild congestive neart failure with field in the costophtenic gutter, as well as mild cardiomegaly with cephalization. Laboratory test results on 31-JAN-2001 revealed a white blood cell count (WBC) of 12.7, hemoglobin of 13 ("initial" hemoglobin also reported as 12.3), hematocrit of 38.5, platelet count of 395000, mild monocytosis of 5.6%, prothrombin time (PT) of 22.3 sec. International Normalized Ratio (INR) of 3.3, sodium of 145, potassium of 4.6, chloride of 111, bicarbonate of 25, glucose of 220, blood urea nitrogen (BUN) of 48, creatinine of 1.3, calcium of 3.3, alaning aminoryangforage (AUT) of 39, appartate aminoryangforage (ACT) of 17, creating kinapa bicarbonate of 25, glucose of 220, blood urea nitrogen (BUN) of 48, creatinine of 1.3, calcium of 9.1, alanine aminotransferase (ALT) of 39, aspartate aminotransferase (AST) of 17, creatine kinase (CK) of 47, CK-MB of 0.9, alkaline phosphatase of 73, total bilirubin of 0.3, cholesterol of 12°, amylase of 31, and troponin I of <0.35. A flat and upright KUB demonstrated normal bowel gas pattern, no free air and no masses seen. The patient was admitted with an initial impression of gastrointestinal bleeding with congestive heart failure, and was treated with a moderate sliding scale and H2 antagonist. On 31-JAN-2001 referoxib was discontinued. Early in the morning on 31-FEB-2001 the patient developed frank gastrointestinal bleeding with melena and burgundy-solored stools, vomited blood, and was transferred to the critical care unit for further treatment. 21-FEB-2001 the patient's primary care physician was consulted. Upon physical examination the patient appeared 'acutely and chronically ill' with blood pressure of 100/70, pulse of 110 and respirations at 18. It was noted to be difficult to obtain any kind of detailed information from the patient, and he was noted to have a catheter in place which he complained severely of. The patient was rather pale, conjunctivae were very pale, there was no edema. Heart had no murmur, snocks, thrills, gallops, or friction rub. Abdominal examination showed a lot of epigastric There was no real rebound or rigidity; nowever, examination was noted to be difficult to perform due to the extent of the patient's discomfort. Additional laboratory test results were reported to reveal a hematocrit of 37, hemoglobin 9.3, and subsequent hematocrit of 28. Stools were noted to be black and tarry. The primary care physician's initial impression was possible bleeding from a Mallory-Weiss tear secondary to the repeated vomiting or from a duodenal ulcer, possible gallbladder disease or pancreatitis, concern for maintaining hemoglobin and hematocrit above 13 due to the patient's pre-existing coronary artery disease, hypertensive cardiovascular disease under treatment, hypercholesterolemia, persistent low back pain sometimes radiating to the left leg prediment, hypercholesterolemia, persistent low back pain sometimes ladiating to the felt leg occasionally to the right leg and occasionally no pain. The patient was treated with vitamin K and transfusion with three units of fresh frozen plasma was ordered "to try to reverse the pro-time", long term anticoagulant therapies for history of repeated myocardial infarctions were reversed gastrointestinal consult was ordered, amylase was to be checked, and a myelogram was recommended. Following transfusion on 01-FEB-2001, gastrointestinal consult examination was performed during which the patient reported feeling better with no chest pain or shortness of breath and somewhat improved applications. The patient denied fever or chilis, loss of weight, headaches throat, dysphagia or odynophagia, dysuria or nematuria. There was no chest pain, palphatrins, coughing or wheezing, but the patient did note occasional shortness of breath. Upon physical & coughing or patient was in no acute districts. examination the patient was in no acute distress, was afebrile with a heart rate of 86 and blood pressure of 112/61. Conjunctivae were somewnat pale and mucous membranes were dry. Carotid pulses pressure of 111/51. Conjunctivae were somewhat pale and mucous membranes were dry. Carollo pulses were 1-, there were no bruits or lymphadehopathy. Lungs revealed scattered wheezes with no crackles. Heart rate and rhythm were regular without murmurs, rubs or gallops. Abdomen was soft with mild epigastric tenderness to palpitation. There was no repound, guarding or masses. Bowel sounds were normcactive and retail examination showed no frank melena. Hemoglobin was noted to have sounds were normoactive and rectal examination showed no trank melena. Hemoglobin was noted to have been 13 at admission, with a subsequent drop to 11, then to 9, and at the time of examination it was 7.1. Initial INR was noted to be 3.3 and, following fresh frozen plasma and vitamin K, it was 1.2. Additional laboratory test results on 01-FEB-2001 lipase was 117, amylase was "normal" (value not specified), sodium was 145, potassium was 4.3, chioride was 111, bicarbonate was 24, glucose was 201. BUN was 81, creatinine was 1.6, calcium was 8.6, ALT was 39, AST was 17, troponin I was



384

MFR Report #:

(continued)

0.035, alkaline phosphatase was 75, bilirubin was 0.3, and albumin was 2.8. Chest x-ray was 'normal.' The gastrointestinal consult physician suspected that the patient had 'an upper gastrointestinal bleed, probably due to a peptic ulcer given his history, as well as non-steroidal anti-inflammatory drug use and [Coumadin]. Additional transfusion was ordered with two units of fresh frozen plasma and packed red blood cells, until hemoglobin was 10. The patient was also to be monitored for worsening congestive heart failure, and upper endoscopy was planned for when INR was monitored for worsening congestive heart failure, and upper endoscopy was planned for when INR was less than 1.5. Subsequently, the patient was treated with furosemide, empiric famotidine (MSD). On 02-FEB-2001 laboratory test results revealed that sodium was 151, potassium was 4.1, chloride was 120, bicarbonate was 29, glucose was 146, BIN was 67, serum creatinine was 1.3, calcium was 3.2. PT was 13.6 sec. PT normal count was 11.3 sec, and INR was 1.4. On 02-FEB-2001 an esophagogastroduodenoscopy was performed. The esophagogastroduodenoscopy was performed. The esophagogastroduodenoscopy was performed. The esophagogastroduodenoscopy was performed. The esophagogastroduodenoscopy was performed. esophagogastroduodenoscopy was performed. The esophagus and duodenum were normal. In the duodenal bulb there was a 1 cm ulcer. There were two flat spots as well as some erythema and minimal oczing from the periphery. The area was washed and the spots did not appear to be raised at all. A small amount of cautery was placed on the periphery of the ulcer and the area was injected with a total of 2 cc of epinephrine in 1:10,000 dilution. Following those maneuvers there was no bleeding from the ulcer, and the ulcer was thought to be at a relatively low risk for re-bleed. As the scope was the ulcer, and the ulcer was thought to be at a relatively low risk for re-bleed. As the scope was brought back in the gastric antrum there was some congested mucosa and a biopsy was taken for Helicobacter pylori. Retroflexion maneuver was performed which showed the stomach to have the appearance of mild gastropathy. Gastritis status post biopsy was noted. The scope was removed. The patient tolerated the procedure well, and there were no immediate complications. The patient was started on lansoprazole (Prevacid), 30 mg daily and a clear liquid diet was initiated. The patient was instructed not to resume aspirin or warfarin sodium until further notice. Findings from the gastric antrum biopsy evaluation revealed mild to moderate chronic inflammation of the gastric mucosa with plasma cells expanding the superficial lamina propria. Some lymphocytes and scattered eosinophils were also seen. There was no significant activity noted and no atypical or malignant features were identified. Modified Writght's stain showed small numbers of Helicobacter Pylori organisms. On 04-FEB-2001 laboratory test results revealed that sodium was 147, potassium was 4.4. chloride was 114, bicarbonate was 30, glucose was 138, BUN was 20, creatinine was 1.1, and calcium was 3.3. On 05-FEB-2001 hemoglobin was 10.8 g/dL and hematocrit was 31.9%. On 09-MAF-2001 the patient was started on therapy with ramipril (Altace). At the time of this report the patient had recovered from the bleeding duodenal ulcer, but continued to receive treatment with lansoprazole, clarithromycin (Biaxin) and metronidazole (Flagyl).



Normal Bance

The elevated BUN, elevated serum creatinine, cardiomegaly, tachycardia, worsening congestive heart failure, mild monocytosis, and cough were considered to be incidental findings. The bleeding duodenal vicer was considered to be immediately life-threatening, disabling, and an Other Important Medical Event. Additional information is not expected.

Relevant tests/laboratory data, including dates

DIAGI	NOSTIC	TEST
DIAGI	103110	1 1

1.

DIAGNOSTIC	201		Data	v	alue Unit	Normal Range
<u>Tests</u>			<u>Date</u>	-	<u> </u>	
blood pressu Comment:	ire measurement 148/59		01/31/01			
cnest X-ray Comment:	mild CHF with f	luid in the costophre	01/31/01 nic gutter	as well as mild	cardiomegaly	w/cephalization
pulse oximet			01/31/01		94 %	
blood pressu Comment:	ire measurement 112/61		02/01/01			
blood pressu Comment:	ire measurement 100/70		03/01/01			
chest X-ray Comment:	normal		02/01/01			
esophagogas: Comment:	troduodenoscopy duodenal ulcer	in the bulb as well a	02/02/01 us oczing 1	n the periphery.	gastritis s/	p biopsy
gastric bio Comment:	psy chronic gastrit	is with small numbers	02/02/01 of Helico	pacter Pylori or	gansisms	

LABORATORY RESULTS

LABORATORY RESULTS	Date	Value Unit	Normal Range
<u>Tests</u>	<u>Date</u>	2 3	150
INE	01 31 01	3.8 12.7	Pb8 17 7601
WBC count	01 31/01	220	He
blood glucose	01 31 01 01 31/01	98.8 F	
body temp	21 31 91	38.5	
hemacocrit	JI, JI, ÓI	13.0	
nemoglobin	31.317.01	12.3	
hemoglopin	21/317/01	9.0	
nemoglobin	01.31?/01	11.0	
hemoglobin	31 31/01	6.5 %	
monocyte count	01/31/01	395000	
placelet count	31/31/01	<0.35	
serum Thi serum alanine aminotransferase	01.31/01	39	

			WATE 01000014	(continued)
	Page 4	MFR Report #:	WAES 01022014	(continued)
serum alkaline phosphatase	01/31/01	73 17		
serum aspartate aminotransferase	01/31/01	25		
serum bicarbonate	01/31/01	48		
serum blood urea nitrogen	01/31/01	9.1		
serum calcium	01/31/01 01/31/01	111		
serum chloride	01/31/01	127		
serum cholesterol	01/31/01	47		
serum creatine kinase	01/31/01	C.9		
serum creatine kinase isoenzyme MB	01/31/01	1.3		
serum creatinine serum potassium	01/31/01	4.5		140 - 148
serum sodium	01/31/01	145	mmol/L	_9 /4:
stool occult blood	01/31/01			
Comment: positive				
	01/31/01	0.3		
total serum bilirubin	01/31/01			
vital sign Comment: pulse 111, respiration 16				
	01/31/01	22.3	sec	
prothrombin time	01/31/01	31		
serum amylase test	02/01/01	2.2		
INR	02/01/01		mg/dL	70 - 110
blood glucose hematocrit	02/01?/01	37		
hematocrit	02/01?/01	28		
nemoglobin	02/01/01	7.2		
hemoglobin	02/01?/01	9.3 0.035		
serum Thi	02/01/01	39		
serum alanine aminotransferase	02/01/01 02/01/01	2.8		
serum albumin	02/01/01	75		
serum alkaline phosphatase	02/01/01	17		
serum aspartate aminotransferase	02/01/01	24	mmo1/L	21 - 32
serum bicarbonate	02/01/01		mg/dL	6 - 20
serum blood urea nitrogen serum calcium	02/01/01		mg/dL	8.7 - 10.5 130 - 138
serum chloride	02/01/01		mmo1/L	0.6 - 1.0
serum creatinine	02/01/01		mg/dL	3.5 - 5.2
serum potassium	02/01/01		mmol/l mmol/L	140 - 148
serum sodium	02/01/01	0.3		
total serum bilirubin	02/01/01 02/01/01	J.,	,	
vital sign	02,01/01			
Comment: heart rate 86				
vital sign	02/51/01			
Comment: pulse 110, respirations 18				
	02/01/01			
serum amylase test Comment: normal				
Comment. Hornar	02/01/01	11	7	
serum lipase test	02/02/01	<u>.</u>		2.0 - 3.0
INR	02/02/01	_	6 mg/dL	70 - 110
blood glucose	02/02 01	2	9 mmol/L	21 - 32
serum bicarbonate	02/02/01	6	7 mg/dL	6 - 30
serum blood urea nitrogen serum calcium	92/02/01	-	2 mg/dL	3.7 - 10.5
serum chloride	02/02/91		0 mmol/L	100 - 108 0.6 - 1.0
serum creatinine	02/02/01		3 mg/dL	3.6 - 5.2
serum potassium	02/02/01		1 mmcl/L 1 mmcl/L	140 - 148
serum sodium	02/02.01		6 sec	10.9 - 13.1
prothrombin time	02/02/01		3 sec	
prothrombin time	02/02/01	± - ·		
Comment: "PT normal count"			0 (-1	70 - 110
blood glucose	32 04 31		8 mg/dL 0 mmol/L	21 - 32
serum bicarbonate	32 34 31	-		6 - 20
serum blood urea nitrogen	32,94,91		0 mg/dL 3 mg/dL	
serum calcium	00/04/01 02/04/01		3 mg/dL 4 mmol/L 1	8.7 - 10.5 7136 - 108
serum chloride	02:04:01 02:04:01	1.	1 mg/dk DR 1	6.6 - 1.3
serum creatinine	52/04/01	4.	4 mmol/L	3.5 - 5.2
serum potassium	02/04/01	14	17 mmo1/L	140 - 148
serum sodium hematocrit	02/05/01		.9 %	42 52
nematodris	12 05 01	10	.3 g/dL	14.0 - 19.5
1200g 2 July 1				



1.

7. Other relevant history including preexisting medical conditions

pertussis; peptic ulcer; nephrolithiasis; myocardial infarction; low back pain; headache; dizziness; ankle sprain
dizziness; ankle sprain
CONCURRENT CONDITIONS: Helicobacter infection; cardiomegaly; congestive heart failure epigastric CONCURRENT CONDITIONS: Relicobacter infection; cardiomegaly; congestive neart failure epigas' pain; hypertension; type 2 diabetes mellitus; tachycardia: spinal stenosis; smoking; serum creatinine increased; penicillin allergy; orthopnea; monocytes increased; intervertebral disc disorder; hypertensive heart disease; hypercholesterolemia; exertional dyspnea; depression cough: coronary artery disease; blood urea nitrogen increased; alcohol consumption

Page 5

C. Suspect medication(s)

- 1. Name (Given labeled strength & mfr/labeler, if known)
 - #1 TAB VIOXX 25 mg

 - #2 COUMADIN Unk #3 TAB aspirin Unk

2. Dose, frequency & route used

- #1 25 mg/DAILY/PO #2 7.5 mg/DAILY/PO
- #3 81 mg/DAILY/PO

3. Therapy dates (from/to) (if unknown, give duration)

- #1 11/30/00 01/31/01 #2 ?/?/96 01/31/01 #3 Unk 01/31/01

4. Diagnosis for use (indication)

- pain, osteoarthritis
 coronary artery disease prophylaxis
 cardiovascular disorder prophylaxis

5. Event abated after use stopped or dose reduced

_,,	YES	NO	N/A	UNK
#1 #2	х			х
#2 #3				Х

6. Lat # (if known)

- #2

7. Exp date (if known)

8. Event reappeared after reintroduction

_ + 0.	.,			
	YES	210	N/A	, JNK
# :			Х	
				X
#2				х
#]				

APR 12 YEST

C. Suspect medication(s)

10. Concomitant medical products and therapy dates (exclude treatment of event)
GLUCOPHAGE
Unk - Unk
LASIX Unk - Unk
NORVASC Unk - Unk
PRAVACHOL Unk - Unk
SLOW FE Unk - Unk



FDA ATTACHMENT

PAGE 1 LAB **LIVE** RUN DATE: 03/21/01 Specimen Inquiry RUN TIME: 0930 ט #: € ACCT #: # LOC: REG: 01/31/01 PATIENT: ROOM: AGE/SX: 77/M pis: 02/05/01 BED: 01 DOB: M.D. REG DR: TLOC: STATUS: DIS IN STATUS: SOUT REQ #: RECD: 02/02/01-1527

SPEC #: RECD: 02/02/01-1527 COLL: 02/02/01-1200 STATUS: SOUT REQ # M.D.

ENTERED: 02/02/01-1528 SP TYPE: SURGICAL OTHR DR: BAMC

ORDERED: STAINGR1, PATHGM4

SURGERY INFORMATION:

Surgery date 02/02/01

Surgeon(s): DR

CLINICAL HISTORY

GI BLEEDING



FINAL DIAGNOSIS

BIOPSIES OF GASTRIC ANTRUM: CHRONIC GASTRITIS WITH SMALL NUMBERS OF HELICOBACTER PYLORI ORGANISMS.

GROSS DESCRIPTION

The specimen is submitted in formalin labeled as "gastric antrum." Submitted are two fragments, 1-2 mm, embedded in total in one block.

Dictated by M.D.

MICROSCOPIC DESCRIPTION

The sections show fragments of gastric antral type mucosa in which there is mild to moderate chronic inflammation with plasma cells expanding the superficial lamina propria. Some lymphocytes and scattered eosinophils are also seen. No significant activity is present and no atypical or malignant features are identified. The modified Wright's stain shows small numbers of Helicobacter pylori organisms.

Dictated by: , M.D. 02/03/01 - 1320 EDIX.JLB

JOB

** CONTINUED ON NEXT PAGE **

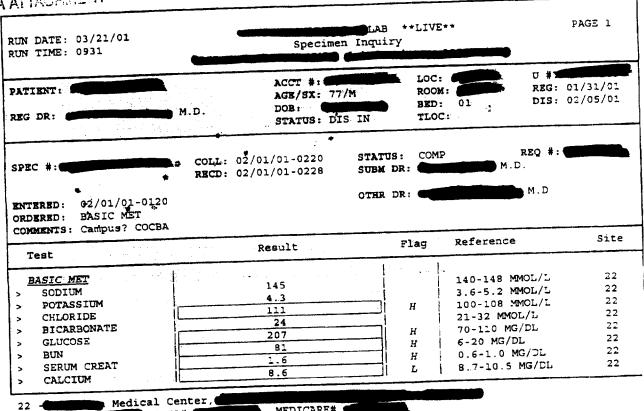
APR 12 PRA

LAB **LIVE**
Specimen Inquiry PAGE 2 RUN DATE: 03/21/01 RUN TIME: 0930 (Continued) PATIENT: SPEC #: CODES: ANTRUM, NOS COPIES TO: BAMC Suite BLK PCS CAS LEV / PROCEDURE DISPOSITION HISTOLOGY: TISSUE ANTRUM, NOS ICD CODES: 535.50 - UNSP GASTRITIS & GASTRODUODENITIS W/O MENTN HEMORG PROCEDURES: STAINGR1 (Incomplete)
PATHGM4 (Incomplete) TISSUES: A. ANTRUM, NOS - BIOSPY ANTRUM M.D. 02/05/01 Signed Signature on file

** END OF REPORT **

WES 17 7.00%

FDA ATTACHMENT



MEDICARE#

CLIA#

CAP#

** END OF REPORT **

RAS 1 7 SUL

FDA ATTAQUEAENT

RUN DATE: 03/21/01 RUN TIME: 0930

MC LAB **LIVE**

Specimen Inquiry

PATIENT:

ACCT #: AGE/SX: 77/M

ROOM: BED: 01

LOC:

REG: 01/31/01

PAGE 1

REG DR:

DOB: STATUS: DIS IN TLOC

DIS: 02/05/01

SPEC #: (

COLL: 02/02/01-0830 RECD: 02/02/01-0836 STATUS: COMP SUBM DR:

REQ #:

M.D.

ENTERED: *02/02/01-0002

OTHR DR: M.D.

ORDERED: BASIC MET

COMMENTS: DATE/TIME 02/02/01

/ 0500

Campus? COCBA

Test 🐗 🔭	Result	Flag	Reference	Site
BASIC MET		1 1		
> SCDIUM	151	Н	140-148 MMOL/L	22
> POTASSIUM	4.1	i	3.6-5.2 MMOL/L	22
> CHLORIDE	120	Н	100-108 MMOL/L	22
> BICARBONATE	29	i i	21-32 MMOL/L	22
> GLUCOSE	146		70-110 MG/DL	22
> BUN	67	Н	6-20 MG/DL	22
> SERUM CREAT	1.3	Н	0.6-1.0 MG/DL	22
> CALCIUM	8.2		8.7-10.5 MG/DL	22

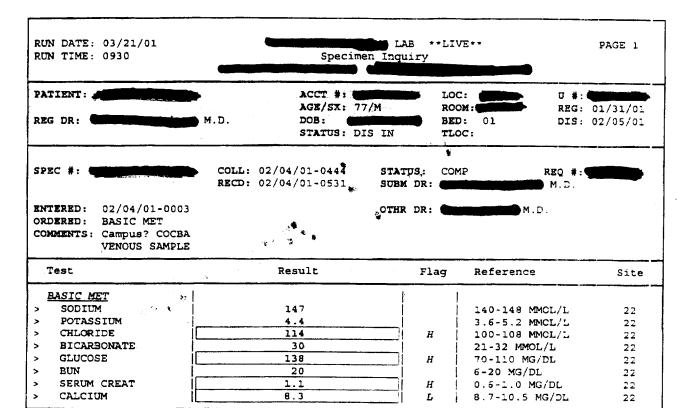
22 - 1 Medical Center 1 CLIA# 🗨

MEDICARE# (

APRIL LIGHT

** END OF REPORT **

FDA ATTACHMENT



CAP# CLIA# MEDICARE#



** END OF REPORT **

PbB 1 1 1660



ealth professionals of a ents and

Page

4. Weight

3. Sex

Product problem (e.g., defects/malfunctions)

required intervention to prevent

permanent impairment/damage

HPGHIRE C

congenital anomaly

disability

4 Date of

6 Cyclif on College Rand ASA feet Light

and from where here fortigen

131 120/48 AT 40 AMME to 160

this report

i / female

male

Form Approved, OMB No. 0910-0291 Expires, 12 See OMB statement on re

THE EDA MEDICAL PRODUCTS REPORTING PROGRAM

2. Age at time

of event:

of birth: (

and/or

Adverse event or product problem

wested - In I Large Meterno wheel

Date

Outcomes attributed to adverse event

hospitalization – initial criprolonged

3/22/66

6. Relevant tests/laboratory data, including dates 3/2

A. Patient information

Patient identifier

In confidence

Adverse event

(check all that apply) death ______

ife-threatening

5. Describe event or problem

3 Date of

event

		duct problems
		or COFFE
		C. Suspect medication(
L	1	 Name (give labeled strength & mfr/lab
s		*1 Celelner
gs		#2 H34
9		2 Dase, frequency & route used
,		#1 111. 91
	•	

#2 Hon	*				
2 Dose, freque	ncy & route use	ed		apy date	es of unknown, give digitation many
#1 - 77).	1 41		# 1	٠,	UK 312.
#2 5/11	1, 4d	٠,	#2		D/ 8/22/6
4. Diagnosis fo	ruse (Indication	7)		1	5. Event abated after use
#1 Call	11/1/12	•		*	stopped or dose reduc
l .	Joinna	/			#1 yes no dee
6 Lot# if know		Exp. da	ate fko	OW.	#2yesnodo∈ arc
#1 5	·	#1			8. Event reappeared after
#2		#2			reintroduction
9. NDC # (for pr	roduct problems	only)			#1 ves no doe
		_			#2 yes no doe
		lucts and	therapy	dates (e)	colude treatment of event)
HCT4	· 2				
XINTI	गुरु हो नुस				
200	71				
D Cupa	<i>५८</i> (ect medica	ما طمية	CO		
Suspe Brand name		л аеч	CE		
2. Type of devi	ice	····			
	ice er name & addre	ess			4. Operator of device
		?\$\$			Operator of device health profession
		ess			<u></u>
	er name & addre				health profession
			ED		health profession lay user/patient
3. Manufacture	REC	EIV)	health profession lay user/patient other 5. Expiration date
3. Manufacture	REC				health profession lay user/patient other
3. Manufacture 6. model #	REC	EIV	01		health profession lay user/patient other 5. Expiration date
3. Manufacture 6. model #	REC	EIV	01		health profession lay user/patient other 5. Expiration date
3. Manufacture 6. model #	REC	EIV	01		health profession lay user/patient other 5. Expiration date modayyri
3. Manufacture 6. model #	REC	EIV	01		health profession lay user/patient other 5. Expiration date modayyri
6. model #	REC	EIV	01		health profession lay user/patient other 5. Expiration date modaysh 7. If implanted, give daysh
6. model #	RECI APR 1	EIV FI 70 TCH	oi CTL	J	health profession lay user/patient other 5. Expiration date modaysyl 7. If implanted, give day modaysyl 8. If explanted, give day modaysyl
6. model #	REC	EIV	OI CTL	not send	health profession lay user/patient other 5. Expiration date moday/yri 7. If implanted, give di moday/yri 8. If explanted, give di moday/yri
6. model #	RECIAPR 1	EIV I 70 TCH	(Do	not send	health profession lay user/patient other 5. Expiration date morday/yri 7. If implanted, give di implanted, give di morday/yri 8. If explanted, give di morday/yri Ito FDA; user on
6. model #	RECIAPR 1	EIV I 70 TCH	(Do	not send	health profession lay user/patient other 5. Expiration date moday/yri 7. If implanted, give di moday/yri 8. If explanted, give di moday/yri
6. model #	RECIAPR 1	EIV I 70 TCH	(Do	not send	health profession lay user/patient other 5. Expiration date morday/yri 7. If implanted, give di implanted, give di morday/yri 8. If explanted, give di morday/yri Ito FDA; user on
6. model #	RECIAPR 1	EIV I 70 TCH	(Do	not send	health profession lay user/patient other 5. Expiration date morday/yri 7. If implanted, give di implanted, give di morday/yri 8. If explanted, give di morday/yri Ito FDA; user on
6. model #	RECI APR 1 APR 1 APR 1	EIV I 20 TCH ion? retu	(Do	not send	health profession lay user/patient other 5. Expiration date morday/yri 7. If implanted, give di implanted, give di morday/yri 8. If explanted, give di morday/yri Ito FDA; user on
6. model #	RECI APR 1 APR 1 APR 1	EIV I 70 TCH	(Do	not send	health profession lay user/patient other 5. Expiration date morday/yri 7. If implanted, give di implanted, give di morday/yri 8. If explanted, give di morday/yri Ito FDA; user on
6. model #	RECI APR 1 APR 1 APR 1	EIV I 20 TCH ion? retu	(Do	not send	health profession lay user/patient other 5. Expiration date modayyri 8. If explanted, give date modayyri but or DA; modayyri clude treatment of event:
6. model #	RECI APR 1 APR 1 APR 1	EIV I 70 TCH ion? retu ucts and	(Do rned to r therapy	not send manufacti da es (ex	health profession lay user/patient other 5. Expiration date morday/yri 7. If implanted, give di implanted, give di morday/yri 8. If explanted, give di morday/yri Ito FDA; user on

proposer when and ducher decords 7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

1. KD. J. (— FTC H & Lo IPM / 30 years PAHX: hypertension, hyperthyruides in authorities SIP athousepy R Imm; breast copst **MEDWATCH** or FAX to: 5600 Fishers Lane 1-800-FDA-0178 Rockville, MD 20852-9787

yes

If you do

the mani

Apr 11 01 04:14p

MEDWATCH THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

by health professionals of adverse events and product problems

14/166 FDA Use Only Triage unit sequence #

THE FDA MEDICAL PRODUCT	S REPORTING PROGRA	^_^^	evening and brook		DAC DAG	
A. Patent Infranct				C. Suspectime.	fication su	
Patient identifier 119	2. Age at time of event: 85	3. Sex	4. Weight	Name (give labele *1 alendronate, a	ed strength and mfr/le	abeler, if known)
In Confidence	Date of birth:	☐ male	or <u>a</u> kgs	#2 2. Dose, frequency,	_	Therapy dates (if unknown, give duration) fromto (or best estimate)
B. Artyersa avento	or product small	,5 rj		#1 10mg qd, 81m	ig qa, /əmg qa	#1
1 X Adverse event a		roduct Problem		#2 4. Diagnosis for use	•	5. Event abated after use stopped or dose reduced
2. Outcomes attributed		— I dinabilibe		#1 Osteoporsis, s	troke prevention	stopped of dose reduced
(Check all that apply	,	disability congenital and	am mby	#2		#1 yes no N/A
[] death	<u>\</u> _	congenical and	=	6. Lot # (if known)	7. Exp. date (if know	wn) #2 yes no N/A
life-threatening (mo	/day/yr) E.	nrevent perma	nent	#1	;#1 #2	Event reappeared after reintroduction
() hospitalization - initi		impairment/da			r product problems of	
	5	Other: Reg	und			#1 yes no N/A
3. Date of	4.	Date of HDS	केलिक्टां द्वा			#2 yes no N/A
event 03/29/	2001 1	his report	04/03/2001		edical products and th	herapy dates (exclude
(mo/day/yr) 5. Describe event or pro		(daylyr)		treatment of event)		
REACTION: UPPER G Patient known to clinic. separate problem. On admission on Dilant 0.625 mg qd, ASA 81m Plavis 75 mg + flovent a osteoporosis with comp on ASA 81 mg already educated on Fosamax 3/29/01 Presented to it hematochezia, hemate SOB than usual. HCT showed melenic stool. 3/31/01 HCT=39.4, HG 3/31 2 Block tarry stool 4/1 EGD showed erosid	HCT was 36 on 3/ in 100mg qhs, Synting, Zestril 10mg., A ind Combivent. Fos when Fosamax start administration cautic actinic with 2 days mests or abdominal now 22.2. BP 119/ T&C 4 units PRBC, is overnight but not c we gastrifts in antrum dign scarring and di	hroid 75 meg qd, dalat 90mg, Fosisamax started arc syphosis and schoted. Patient was ons. of dark stool with pain. Noted moi 64. Rectal exam, and give 3 units diarrhea in and 0.5 to 0.75 uodenitis. H pylo	Premarin amax 10mg qd, aund 10/99 Hx losts. Patient carefully cout re tired and stat. cm ulcer in the	6. model # 3 VI E Catalog # serial # lot # other # 9. Device available	ECETVE APR 1 2 2001 WATCH C	iny user/patient other: 5. Expiration date (mo/day/yr) 7. If implanted, give date (mo/day/yr) 8. If explanted, give date (mo/day/yr) not send to FDA)
 Relevent tests/labora 	tory data, including o	dates 🕠		yes	<u> </u>	ed to manufacturer on
		20me	hanged ilusec ad - which of the off hasa	event) E. Florenston Ser 1. Name, address, i	e confidential ty	Phan D.
7. Other relevant history allergies, race, pregnand dysfunction, etc.)				2. Health profession yes no 5. If you do NOT wa		4. Also reported to manufacturer user facility

Mail to: MedWatch

or FAX to:

5600 Fishers Lane

1-800-FDA-0178

Rockville, MD 20852-9787

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTV141166

DSS



For VOLUNTARY reporting tealth professionals of adverse vents and product problems

Form Approved, CM8 No. J910-0291 Expires:12/31 See OM8 statement on reve

Triage and sequence # 141207

	rage	_ or	<u></u>	
A. Patient information		C. Suspect medicati	ion(s)	
Patient identifier 2. Age at time	3. Sex 4. Weight	1. Name (give labeled strength 3.		
af event:	Temale bs	" Onoxapan		
Date		1 CO	+	
In confidence of birth:	male kgs			
B. Adverse event or product proble	m	2 Dose, frequency is routefused	Therapy date	es funknown, give juration
Adverse event and/or Product problem	(e.g., defects/malfunctions)	1 30m JA 94	#1 rec	
2. Outcomes attributed to adverse event (check at that apply) (disability	•	12 work dose 90	1 22	
Congressial	anomaly	4 Diagnosis for use ringication		
	ntervention to prevent	at 1		Event abated after use stopped or dose reduce
lica-litrostonico	t impairment/damage	LAX CVA		#: Tyes Ino Tigges
hospitalization - chilal or prolonged other:		12 MY CVA		apck
3 Date of 4. Date of			Exp. date of snown,	≠2 _yesncdoes
event 129 CC this report	11-7-01	#1 #1		d Event reappeared after
5. Describe event or problem	4 - '	#2 #2		reintroduction
			, t.	*1
Suspected Drug: Enoxaparin 30mg SQ qd	+ ASA qd (dose	9. NDC # (for product problems cn.]	- Goos
not given)	Lblerd (3)	-C Connection		=2 yescgoes
Reaction: Hematemesis, severe anemia, UG		10 Concomitant medical product	ts and merupy dates lex	Coude resomen of event.
PMH: PSVT, HTN, migraines, osteoarthritis		508 med	blut	`
hypercholesterolemia, depression, non-ulcer	· · ·	000	0000	
recurrent CVA (on Coumadin in past but erra	·	6		ノ
switched to Enoxaparin recently), multiple in				
HPI: 78 yo F, 60", 41kg, presented 12/29 wi		D. Suspect medical	device	
x past 2 weeks, weakness, unable to walk sin	ce 12/25.	1 Brand name		
		2. Type of departe.		
Epistaxis x past few days. VS BP 95/63, HR		*		
sat 94. Black stool strongly heme +, NG tube		3. Manufacturer name & address		4. Operator of device
in stomach. Per GI consult: UGI bleed likely		HEC	EIVED	Teaith professional
ASA ingestion aggravated by Enoxaparin, as	well as probable			av usenpatient
vit K depletion	4	APR	1 2 2001	siner
Labs: initial EKG: sinus tach + inferolateral	- 1 1			
CPKs NL, WBC 26.5H, Hgb 4.5C, Hct 13C,	1 1	LMFNWA	TCH CTU	5. Expiration date
L 5, PT 23.1 H, INR 3.11, PTT 44, Na 137, I		5.		(maday-yr)
Cl 108L, Gluc 199H, BUN 60H, SCr 1.8H, E	3UN/SCr = 38.3,	model #		
Digoxin 1 ng/ml, H pylori negative		catalog #		7 If implanted, give date
SH/FH: No alcohol or tobacco use	.,			mo dav. //:
Allergies: NKA (Hydrocodone - n/v, Verapa	וחוו-	serial #		
constipation) Meds: Robaxin 500mg po q8h prn, Lanoxin	0.125mg no ad	lot #		8. If explanted, give date
Lescol 40mg po qd. Lovenox 30mg SQ qd, A		other #		
Cimetidine 400mg po qd, Multivitamin qd, V		9. Device available for evaluation?	? (Do not send t	d SDA)
Lopid 600mg po qd, Toprol XL 50mg po qd,		yes nc	<u>.</u>	
1 po q 6-8 h pm. Phenergan 25mg po pm	1 1 3	10. Concomitant medical products		mg day-s
Treatment: Admit to hospital, O2 per NC, I'	V NS Amnite	ve serves measure p. odders	a. dlerapy dates (exc	iude treatment of event
PRBCs, Vitamin K 2.5mg po, GI consult, E0				
Phenergan, Cardiology consult: no MI, Per E	• • • • • •			
ulcer confined to apex of duodenal bulb with		E. Reporter (see confid	entiality section of	on back)
oozing, hiatal hernia, probable Barrett's esop	, 1 7	1. Name, address & phone #		on edek)
Outcome: Discharged 1/1/01 in improved co	- 1	R	ph	ca ic
Lanoxin, Prevacid, Toprol, KCl, Sorbitol and				
qd	- i l 🛉	-		
- 1		9:6-		-
CTU141207	[2	2. Health professional? 3 Occu	patron 4.	Also reported to
Mail to: MEDWATCH OF	FAX to:	Tyes To Pha	rmacist	manufacturer
5600 Fishers Lane	1-800-FDA-0178	5. If you do NOT want your identit		user tactifity
Rockville, MD 20852-9787		the manufacturer, place an " X "		distributor



BOLUNTAL TO THE STATE OF THE ST

e garage

FD4 Use Only
Triage unit sequence i 141188

DANC THE TIDA MEDICAL PRODUCTS REPORTING PROGRAM Page C. Suspect medication(s) Patient information 1 Name (give labeled strepgth 8 mfr/abelor if known 4. Weight 3. Sex Patient identifier 2 Age at time of event: female 52. ∰ Oate male | of birth Therapy dates of Astroatic painting Dose, frequency & route used B. Adverse event or product problem Adverse event and/or Product problem (e.g., defects/malfunctions) Outcomes attributed to adverse event disability (check all that apply) 4 Diagnosis for use (indication) Event abated after use congenital anomaly death stopped or dose reduced 5. L. 3 3 3 required intervention to prevent [] Ma-threatening # **X**ycs ∏no ∏doesn permanent impairment/damage 🔀 misponizator i inballor pacetyjed ag Vas Engling doesn Date of 4/6/01 Event reappeared after this report event reintroduction Describe event or problem \$1 ∏yas ∏nc Kogcesn' who day to story at red block NDC # ifor product problems on y. was the same that the black Concomitant medical products and therap, cales revolude treatment Charles Epicater per - Con performed to may book 4 D. Suspect medical device 2 Type of device 3. Manufacturer name & address Operator of device neutral rulessin -ay user-patient RECEIVED I was bout Expiration date model # 7 If implanted, give date Relevant tests/laboratory data, no uding cares catalog # 9 8 100 serial 🖺 ma 0,55 8. If explanted, give date lot # Denor send to FOA 9. Device available for evaluation? The second from an Assistance 12 6 6 1 1 1 2 6 p. 1 3 10. Concomitant medical products and treads bases കാലമുന്നുമാന് വിദ്യ averd office it is stilled 6 103 Other relevant history, including preexisting medical conditions (e.g., a lergic) race pregnancy, smoking and alcoholluse, hepatic/renal dysfunction letc.) History Michel + Society E. Reporter (see confidentiality section on back) Name, address & phone # for floor for a good that mountains Health professional? 3 Occupation Also reported to rnanufacturer PP:-Y∐ yes ∐ no Mail-to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: user facility 1-800-FDA-0178 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.

THE FDA MEDICAL PRODUCTS REPORTING PROCRAM

orting lverse ems

FDA LISE ONLY

3707352-6-00-01)LUNTARY repo h professionals of ad s and product proble
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A. Patient in formation	C. Suspect medication(s)	
3. Sex 4, Weight	Name (give labeled strength & min/labeler, if known)	
of event: 66 yo femals 230 bs	" ASPICIA	
261763 Dete In confidence of pirm:	#2	
B. Adverse event or product problem	Dose, frequency & route used Therapy dates (transition for best entires)	(il unknown, give duration)
Adverse svent and/or Product problem (e.g., defects/malfunctions)	#1 #1	
2. Outcomes stributed to adverse event	#2 #2	
(check all that apply) disability congenital anomaly	4. Diagnosis for use (indication) 5.	Event abated after use
death required intervention to prevent	[#1]	stopped or dose reduced
Ine-Inreatening permanent impairment/damage	#2	yes no Scoesn's
hospitalization – initial or prolonged Other		yes no deesn't
3. Date of event 2/20/00 4. Date of this report 4/7/0/	1	Event reappeared after
5. Describe event of problem	#2 #2	reintroduction
	9. NDC # (for product problems only)	yes no deesn't
· upper GI bleed- severe anemia	#2	yes no deem'
a Itala and restrict ulcour	10. Concomitant medical products and therapy dates (exclusive)	ude treatment of event)
managine jornali gravne cocers		
multiple pmall gestine ulcers and erosions - acute duoudenal		
elcer - Higtus Hernia	D. Suspect medical device	
	1. Brand name	
a 1 1 51 ant of blood		
· packed cells - 3 units of blood	2. Type of decice	
Biven .	3. Manufacturer naine & address	4. Operator of device
		health professional
· pepcid Ivdrip - iron supplement		other:
peper	n=a=v=n	J. S.
guen	HEOKIVED	
	6.	5. Expiration date (modeyryr)
	model # APR 1 9 2001	
Relevant tests/laboratory data, including dates	MEDWATCH CTU	7. If implanted, give date more involved
· loophagogastroduodenoscopy	sortal 5	
- sopragogasva utcomo no zao		& K explanted, give date
1	lot #	(maidspyr)
* Hg = 8.2 HCT = 22.9	other # 9. Device available for evaluation? (Do not send to	FIDATO
	yes no returned to manufacture	erm 1000
	10. Concomitant medical products and therapy dates (excl	(mode/n) lude/treatment/of eyent)
		APR 1 9 2001
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dystunction, etc.)		
Hiatus Hernia	E. Reporter (see confidentiality section of	on backt
HTN	Pharma Pharmas a phone of the pharmas on the star and	
, , , ,	Hasota and	Medica Center
APR 18 2001		
	2. Health professional? 3. Opcupition	. Also reported to
CTU 141575	- Charcala	manufacturer
Meil to: MEDWATCH or FAX to: 5800 Fishers Lane 1-600-FDA-0178	yes no Pharmas	user facility
Rockyllia MD 20852-9787	5. If you do NOT want your identity disclosed to	distributor



THE FOA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting nealth professionals of adverse vents and product problems

nuernet Submission - Page 1



Form Approvad OMS No. 0910-0291 Expires: 04/30/01 See OMS statement on reverse

Triage unit sequence # 141750

A. Patient infor	mation			C. Su	spect med	alcation	5)			
Patient identifier 2. A	ge at time f event:	3. Sex	4 Weight	1. Name #1 ASA	(Product Name) (Lab	eled Strength)	/ (**	Vifr/Labeler)
300 5 0774 or		female	or lbs	Warf	arin	-'/		/		
	eate If birth:	male	66kgs	#2			3 Therapy date	/ os (funkci	own bive o	uration)
B. Adverse eve		problem		2. Dose/Fr #1 325mg	equency/Route	used / _{Oral}	From #1		To (or best	
. Adverse event	and/or Prod	uct proble m (e.g., defects/	matfunctions)		/bid	/				
2. Outcomes attributed t	o adverse event	disabil ty	ŀ	#2 2mg		Oral	#2			
(check all that apply)	; <u>.</u>	congenital anomaly			sis for use (sep	arate indications	s with commas)		abated afted or dose	
	md/yyyy)	required intervention to permanent impairment/	prevent damage	#1				#1 [1] ye	s 🗌 no	doesn't
life-threatening hospitalization – ini	itial or prolocized	other:		#2						
nosp talization = ill	itta: di proisingeo			6. Lot#(i	f known)	•	date (if known)	#2 🗹 ye	s i no	doesn't apply
3 Date of event	4	Date of this report 04/20/2	2001	#1		#1 			reappeare	d after
5 Describe event or pro	blem	(⊤m/dc/yyyy)		#2		#2		i	s _ no	doesn't
GI bleed	Joren .			9. NDC#	(for product pro	olems only)				
					-	-		#2jye		doesn't
				10. Conc	omitant medica	l products ar	nd therapy dates (ed 2 unit:	exclude tre	atment of e	vent)
ı				D &	uspect me	dical de	vice			
				1. Brand	name	, arear ac	V100			
				2. Type o	of device					
i				3. Manuf	acturer name &	address		4 0	perator of	device
								<u> </u>		ofessional
					F	RECI	EIVED) =	lay user/g	patient
						APR 2	2 3 2001	5. E	xpiration o	late
			,	6. model #	M	EDWA	TCH-CT	IJ <u>_</u>	implanted	I, give date
6. Relevant tests/labora	atory data, including	dates		catalog i	t				mm/dd/yyyy)	., .
13.5/42-4/11-	-:7.4/22-4/1	2-:10.1/30-4/1	3-	serial #						
INR: 5.89-4/1 er.doscopy 4/1	11-:8.15-4/1	2-;1.89-4/13-		lot #				- 8. H	explanted	l, give date
				other#						
					e available for		,	end device		
				y		-	returned to manufa		(mm	(dn/yyyy)
				10. Con	comitant medic	al products a	and therapy dates	(exclude tr	estment of	event)
2 21 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	a including proprie	ting medical conditions		-						
(e.g. allergies, race, pre	egnancy, smoking and	alcohol use, hepatic/renal d	lysfunction, etc.)						
				E. F	leporter (s	see confide	entiality secti	on on b	ack)	
		•		1. Nan	ne		phòne			
		_		dame	,	#		Ave	Inpat	チンし
		APR 20 2001		Pharm	Hospi acy	LdI		* (700
		" 711 22		4	d Character			R		9 9 6
		~ <001			d States th professional	? 3. Do	ccupation	4 /	Also report	ted to 70
C-TV14	7			┙ӶѾ,	•		tealth Professio	nal [manuta	
	Mail to: MEDWA	TCH or FA	AX to: 800-FDA-0178	5. If yo	u do not want y nanufacturer, p	rour identity d	isclosed to		user tai distribu	

	PHARMACY		[Z] 0 0 1 83
04/24/01 TUE 08:32 FAX Individual Safety Report	ofessionals of adverse	Triage unit	ተ የ
	ad product problems	141916	7 🐔
LANKER YAR ORDER ERE COME EREN EREN DER HAN HERRE DER EREN EREN EREN EREN EREN EREN E			\$
#3710502-9-00-01*	dicatio	on(s)	
	The state (New 1800 Etc. 311 or 311	h/labeler, if known)	
Patient information 3. Sex Weigi	has 11. Name (greater)		
atient identifier 2. Age at time of event:	- 10s 11 7 10 0 12	ave duration	- 1
or Date	kgs 2 A50)01 route used	Therapy dates (if unknown, give duration) tonical (or best estimate) Therapy dates (if unknown, give duration)	
at bleth:	2. Dose, frequency	Dron to Admora	* *
coolidance	ms 1 25h product	1 1 1 1	_ ,
Adverse event or product problem (e.g., delects/mallunch	1 2 335 Day Duck	5. Event abated after use stopped or dose reduc	ed t
Adverse event disability	4. Diagnosis for use (indication)		
ne that appry)	1 1 " CAD"		T .
death		a2 ☐yas ☐no ☐do	Py
T ide threatening	6. Lot # (if known) 7	Exp. date (il known)	
nospitalization - initial or prolonged	B. Low part of the state of the	reintraduction	/ '
4. Date of 3/2./4.		92 #1 ☐ yes ☐ no ☐ 48	pply
avent 3/4/01 (modes/yr)	9. NDC # (for product problems	only) #2 yes no	PPRY
Describe event of problem	9. NDC # (for process	forchide treatment of event	<u></u>
10 1/20 7 3.1. bkeb-	10. Concomitant medical pro-	ducts and therapy dates (exclude treatment of event	1 1
Describe event of problem Pt Admitted T. g.i. bired. Aute as being due to carrot g ASA & Plavix in Hop	report 1 Carling 100	•	1
1 to as been due to	rana Cardisenco		
MA WE TO HAP	Inlu		
as ASA & TRAVIA	Ancest	al davice	
ASA & Train 2001	D. Suspect medi	cal device	11
D) to so back or from	1. Brand name		
400 0	2. Type of device	4. Operator of dec	vice
Dis Charge	3. Manufacturer name & ad	dress health profe	ssional
O	3. Manufacture.	lay user/pa	theit lait
•		omer	11
	11		
	11	S. Expiration da	te
	11	(mords y/Yr)	11
	6.		
	model #	7. If implanted,	dive awa
1 - 1100	catalog #		!
6. Relevant tests/laboratory date, including dates	portal P	8. Lexplanted	, give date
7/4	1 1	(marday44)	
13.6 (11-142)	lot #		
1.34	Other f	valuation? (Do not send to FDA)	
PT 13.6 (11-142) ,NA 1.34 Phillets 273 (140-440)	9, Device available	o returned to manufacturer on	ayori Leventi
Ph. weeks 273 (190-440)	Secontiant madic	al products and therapy dates (exclude treatment of	
	e.g. aftergies.	J 3	· i
	- allarnies Swaring		
7. Other relevant history, including pre-zisting medical conditions (etc.)	ee confidentiality section on back)	š
lace broateness	E. Reporter (phone !	
CAN	1. Name, address 4	W 7 5	ر ا
maris - 8.1. bleed		forpital apply	interes
10129.		Asspiral 100 25	711111
Dragness - 8.1. bleed, CAD		Fue Va Also report	ed to
10 mg 1 mg	2. Health profession	ii7 3. Occupation manu	facturer
		J-harmacist _ user!	
W. TOLAPO OF FAX	O: 40 NOT W	of your Identity disclosed to distrib	bertor 🔆
Mail to: MEDWATCH APP or FAX 1-800	FDA-0178 5. If you do NOT we the manufacture	r, place an "X" in this box.	to the event.
Rockville, MD 20852-97672001	Whate an admission that medical person	onnel or the product Causes 5	"Lagran
FDA Form 3500 (6/93) Submission of a report does not Edns	Minis die America	r, place an "X" in this box. Use] onnel or the product caused or contributed	STATE OF THE

Cru 141916

REPRODUCTION OF ORIGINAL INCIDENTAL SAFETY REPORT	RY reporting by	Form Approved:	OMB No. 2910-029 Expires 11/3k/99 Sec OMB scalesment on reverse
	oduct problems	Triage unit	142129
3710831-9-00-01 Patient information		medication(s) beled strength mfr/labele	if known)
118 of event: 34 or male	#1 Asyldo	The state of the s	<i>k</i>
n confidence Date of birth 3. Adverse event or product problem	2. Dose, frequer	cy routs used 3. There	oy dates (If unknown, give
Adverse event and/or Product problem (e.g., defects/malful Dutcomes attributed to adverse event			
(Check all that apply) I death (mo/day/yr) disability HA I death (mo/day/yr) congenital anomaly I life-threatening required intervention to p Shotoitalization - Inital or prolonged	4. Diagnosis for	use (indication)	5. Event abated after use stopped or dose reduced system in doesn't apply
D. Dabe of 6/20/00; 4. Date of 4-24-	6. Lot # #1	7. Exp date #1	5. Event reappeard after
5. Describe event or problem Adverse reaction was - Upper GI bleed, High decreased to 3, respiratory distress	#2	#2 aduct problems only)	reintroduction ##]res no beforesn't apply
Treatment of ADR was - DC aspirin, PRBC transfusions	10. Concomitar treatment of ev	it modical products and the	rapy dates (extrade
		ed medical device	
Severity was - Severa Causality based on Naranjo was - 5 probable	No. 100 (100)		
i. Relevant tests/ laboratory data, including dates			
Allergies - PCN Due to known drug all			
Due to drug interactionDue to dose related re	100000000000000000000000000000000000000		
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and a use, hepatic/ renal dystfunction, et RECEIVI		need 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
APR 2 6 20	1 2 2 2 2 4 4 4	er (see confidential	ty section on back)
MEDWATCH	CIU	Modical Center	Also and by
FDA Mail to: MEDWATCH or FAX to: 1-806 CDC Rockville, MD 20852-9787	0178 E Viscou do NO	assonal? Ino Drug Info Special want your identity disclosed to	The same function 1

APR 25 2001

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Individua	1 Safety Report
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/ 48	MEN MIR HET Ber tat ifent, enter nern trent reimt ter sen,
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professionals of adverse and product problems

CDER

Triage unit sequence it / 42349

A MANAGEMENT AND THE COMMITTEE AND	(1) (1) BA [
+3714537-1-00-01+ 1ge /	C. Suspect medication(s)
A. Patient information 1. Patient identifier 2. Age at time of event:	C. Suspect medication(s) 1. Name (give labeled strength & mfr/labeler, if known) #1 P
life-threatening permanent impairment/damage Mail hospitalization - initial/or prolonged other:	#2 CA #2
Receive J Bland Transfusion (40.45) + discharged on ASA	Unclear but yours. Hy received Inducin in recent days PTA D. Suspect medical device 1. Brand name
CGD should engrixmately 13 Ulcers - Antral in location per GI dictors note	2. Type of device 3. Manufacturer name & address RECEIVED 4. Operator of device health professional lay user/patient other: MAY 0 1 2001
6. Relevant tests/laboratory data, including dates H. Pyloni (*) SC-= 2.0, BUN SZ K+5? Hyb 76 Het 22.7 Pl.fel, t 328 Disclude L. L. S	6. MEDWATCH CTU **Todayyri **Todayyri 7. If implanted, give date (mordayyri) 8. If explanted, give date (morday/ri) other #
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)	9. Device available for evaluation? (Do not send to FDA) yes no returned to manufacturer on (morday/yr) 10. Concomitant medical products and therapy dates (exclude treatment of event) E. Reporter (see confidentiality section on back) 1. Name, address & phone #
CAD, HTM. AF.b, T Cholo sterl Use & Inducin up to lak prior to alm issue for Shirlder prior Mail to: MEDWATCH or FAX to: 1-800-FDA-0178	2. Health professional? 2. Health professional? 3. Occupation Also reported to manufacturer was facility 5. If you do NOT want your identity disclosed to
Rockville, MD 20852-9787 F(A Form)35(3)49(3)4 Zubinission of a report does not constitute an admis	the manufacturer, place an "X" in this box.



OLUNTARY reporting ilth professionals of adverse nts and product problems

Internet Submission - Page 1

Form Approved: OMB No. 0310-0391 Expires: 04/30/3 See OMB statement on revers (

FDA Use Only	. •
Triage unit sequence#	142643

	PRODUCTS REPOS	TINC PROCES		tuer annu	11331011	ugo .	*1 1			
HE FDA MEDICAL	PRODUCTS REPO	KIING I KOULIII			0.0.		adication	12		اكتسم
A. Patient in	formation						edication((Mfr/Lat-	eler)
Patient identifier	2 Age at time		3. Sex	4. Weight	1. Name Warf	(Product Na	me) (Lab /2.5mg	eled Strength)	/DuPont	sier,
	of event: 77	Years	female	lbs	#1 Warr	3 E 111	/ 2.5	,	/ 	
3550	or ———			or	#2 ASA		/81mg		1	
	Date		✓ male	70kgs						us duration)
In confidence	of birth:			kgs		equency/Ro	ute used	3. Therapy date	s (IT JNKNOV™, g ' Tu 'or i	est estimate)
B. Adverse	event or proc	luct proble	em		#1 2.5m	g /qD	/Oral		96 - 03/29	
Adverse ever		Product proble m	(e.g., defects/n	nalfunctions)						
··	ited to adverse event				#2 81mg	$/_{dD}$	Oral	#207/28/19		
(check all that app		i uisability			4 Diagno	sis for use (separate indication	s with commas)	5 Event abated	after use
death		_	al anomaly		#1 A-Fi	b.			stopped or de	ose reduced
_	(mm/dd/yyyy)	✓ required	intervention to p int impairment/d	prevent	1 1 "				#1 🗹 yes 🛄 n	io doesn't
ife-threatenin		_ `			#2 ASHD					- doesn'
hospitalization	n – initial or prolonged	other: _			6. Lot#(7 Fxn	date (if known)	#2 🖍 yes 🔝 n	doesn' apply
		4. Date of			#1	: KIIOTTI	#1		8. Event reapp	eared after
3 Date of event 03/2	9/2001	this report	05/03/2	001	l "''				reintroducti:	
(mm/dd/yyyy)		(mm/dd/yyyy)			#2		#2		#1 [] yes 🗹	no Tildoeso'
5. Describe event of	or problem				NIDC #	(for product	problems only)			
Patient who	failed to	notity	et eian	of	3. NDC #	(101 Product	p. 20.0.1.0 0.11,7		#2 yes 🗹	no doesn' apply
anticoagul	ation provid	ier at III	ac argir	~-	<u> </u>	IA	the land and the ar	nd therapy dates (e		
tarry stoo	ls developed	. GI NIEGO	econdary		10. Conc	omitant med	icai products a	il, doxazo	ngin KCl	
dehydration	n, and hyper d INR -5.9	Vateura 2			Amlo	upine,	ristuobi	Metolazor	DELLY NOT	'
to elevated	L INK -3.9				algo	kin, Fu	rosemide,	y vitamin	,	
1					arib;	ızıde,	neburoroa	y vicamili.	•	
					1 1					
					D 6	Langet 1	nedical de	vice		
							nearcar ac	VICC		
					1. Brand	name				
				•	2 Type	of device				
}										
			*	· · · · ·	3. Manu	facturer nam	e & address		1 ~	of device
			100	-	11				1 :=	h professional
					1		DEC	EIVEL	ayu 📋 ayu	iser/patient
									ノ [] othe	7
					1					
					11		MAY	0 4 2001		
					1				5 Expirati	on date (∧)
1					6.	٨	JEDWA	TOH OT	111	
					model #		ALC D AAN	-1-V+1-V- 1	V	
6 Polevant tests	laboratory data, incl	uding dates			catalon	#			_ /. If impla _ (mm/dd/y)	nted, give date (yy)
0. (6)0000		_			11					
					serial #					
					1				8. If expla	nted, give dat ક ૧૧૪૪)
}					101 7					
1					other#					
1					9. Devi	ce available	for evaluation?	•-	end device to EDA	व
						yes	no	returned to manufa	acturer on	(mm/ckl/yyyy)
					10 Co	ncomitant m	edical products	and therapy dates	(exclude treatme	nt of event)
							• • •			
			al conditions							
7. Other relevant	t history, including p ce, pregnancy, smokin	reexisting medic	ar conditions . hepatic/renal d	lysfunction, etc.)					
(e.g., allergies, rac	stive heart	failure	2.			Zoporto	r (see confid	entiality secti	on on back)	
1. Conge	erotic heart	disease.					See conne	phone #		
Atrial fi	brillation.	on Coumac	lin. 4.		1. Na			, , , , , , , , , , , , , , , , , , , ,		<u></u>
Chronic r	enal insuff:	iciency Wi	ith BUN b	n			harmD	dan Mari		
the low 1	.00s. 5. T	ype 2 diak	oetes, or	ı	VA P	SHCS, 166	33 S. Columb	oian way		
oral agen	its. 6. Br	adycardia.			Seat	tle		Washington	1	98108
Hypertens	ion.					ed State	ε 👚		ed.v:1.9	
1 /	1110100	i,	71			ith profession	onal? 3. C	Occupation	1 .	eported to
ICTV/	42645		111	<u>. </u>	- [☑	yes	no Pharm	acist	1 :=	anufacturer
	Mail to: MI	DWATCH	6151	ŠĶ.to: €06-FDA-0178		·	ant your identity	disclosed to	st	er facility
	56	00 Fishers Lane	ik 1	606-FDA-0178	D. If y	manufactur	er, place an "X" i	n this box.	die	stributer
كـــالكا اا	Ro	00 Fishers Lane ockville, MD 208	5 52-97 87							

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

OLUNTARY reporting th professionals of adverse ts and product problems

Internet Submission - Page 1

FDA Use Only

Triage unit

A. Patient infor	rmation				C. Sus	spect m	nedication(s)	
1. Patient identifier 2. A	ge at time fevent: 81 Y	ears/	3. Sex female	4. Weight	1. Name #1 Celeb	(Product No		eled Strength)	(Mfr/Labeler)
D	ate		male	or	#2 Aspir	in	/ 325 mg	3	7
In confidence of	f birth:		Inale	kgs	2 Dose/Fre		/	13 Thorany dat	es (if unkrown, give duration
B. Adverse event		ct proble		nalfunctions)	#1 200 mg	/QD	/Oral	From	To (or best estimate: 001 - 01/25/2001
2. Outcomes attributed to	o adverse event	disability			325 #2 mg	/QD	/Oral		001 - 01/25/2001
(check all that apply)		congenita	l anomaly			is for use (separate indications		5. Event abated after use
death	dd/yyyy)	= -	ntervention to p	revent	#1 Arthr			,	stopped or dose reduce i
life-threatening			it impairment/d		- Anthon	itia a	ad ayaayaabi	L. HENVEND	#1 ves no does!
hospitalization – init	tial or prolonged	other:			<u> </u>		nd presumabl	y HIN/CAD	
3. Date of		4. Date of			6. Lot # (if I	known)		date (if known)	#2 ye: no does)
event 01/25/20	001		05/04/2	001	#1		#1 ———		Event reappeared after reintroduction
5. Describe event or prot	blem	Vau			#2		#2	!	
81 year old Af					9. NDC # (f	or product p	roblems only)		#1 yes no does i
presented to to complaints of						-	-		#2yes nodoes i
prior. Patien					10. Concor	nitant medi	ical products and	d therapy dates (e	exclude treatment of event)
Emergency Room		History							. 10 mg TID,
Arthiritis, HT	N, CAD, Hy	pothyroi	dism.	}				medex 10 Ç	;D -as
Patient was st					listed	on ac	lmission-		
Celebrex 15 da				,					
In ER - Patien blood in rectu			n-colore	ea	D. Sus	spect m	nedical dev	rice	
Endoscopy indi			c ulcer	. i	1. Brand na		ioanoai ao.	.00	<u> </u>
no active blee				·					
Patient denied				1	2. Type of o	device			
dysuria, cough		g Hospit			3. Manufac	furer name	& address		4. Operator of device
course, patien							u 400.033		health professional
Colonoscopy pe		d WNL. Patient							ay user/patient
during hospita									the:
dinitrate 10mg				, ,					[
levothyroxine									
discharged 1/3	0/01.				6.		 	-11 /1-1-	5. Expiration date
					model #		HECE	ニノヒレ)
6. Relevant tests/laborate	ory data, including	dates			model if				7. If implanted, give date
1/25/01 WBC 14			.1;	1	catalog # _		MAY0	7. 2001	immrdd/yygy)
1/28/01 WBC 9.)1	seriai #				
WBC 8.2. 1/25						M	FNWAT	CHCT	8. If explarted, give date
2.14; 1/27/01				· ;	lot #			<u> </u>	(mm,dd/yy;y)
1/29/01 RBC 3. 1/26/01 Hgb 11					other#				
1/28/01 10.7;				1	9. Device a	vailable for	evaluation?	(Do not sen	d device to FDA)
Hgb 10.3. 1/2					☐ yes	Li	no rel	turned to manufact	(inm/dd/yyyy)
20.8; 1/27/01		1/28/01	Hct 30.2	2;	10. Concon	nitant medi	cal products and	therapy dates (e	exclude treatment of event)
1/30/01 Hct 30									
7. Other relevant history, (e.g., allergies, race, pregna				unction, etc.)			*		
81 yo African			_	1	. E D.				
with a rolling	, walker. N	KDA. De	nies	51		orter (tiality section	n on back)
current tobacc		hol use.	Patier	ıt [1. Name		pr	none #	
stated that sh			41 F	İ					
esophagogastro				.d	\	Hosp,			JCX
that she start				-~					
Aspirin about				at.	United				
			<u> </u>		2. Health p			-	4. Also reported to
	fail to: MEDWA	тсн	or FAX t	o:	<u></u> yes		no Pharmacis	· · · · · · · · · · · · · · · · · · ·	manufacturer
	5600 Fish	ners Lane , MD 20852-9	1-800	-FDA-0178			our identity disc		user facility
	Rockville	, MD 20852-9	JANIES	4 200			lace an "X" in th		d stributor
FDA Form 3500	Submission of a	a report does	not constitut	e an ation (s io	that medica	personne	or the product	caused or conf	tributed to the eve nt.



For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 32.4.7

B6. Relevant tests/laboratory data, including dates continued

1/25/01 PT 15, INR 1.2, APTT 21. 1/27/01 Na 143, K 3.5, Gluc 80, BUN 9. 1/30/01 BUN 9, SCr 0.4, Ca 9.0, Mg 1.8, P 2.8.

Mail to: MEDWATCH

or FAX to: 1-800-FDA-0178

5600 Fishers Lane Rockville, MD 20852-9787

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the eve nt.

/OLUNTARY reporting alth professionals of adverse nts and product problems net Submission - Page 1

FDA Use Only Triage unit sequence #

HE FDA MEDICAL	PRODUCTS REPOR	TING PROGRA	<u> </u>	ernet Subn
	formation			
Patient identifier		Years	3. Sex	4. Weight
171	or ————		[] female	or lbs
In confidence	Date of birth:		✓ male	6 <u>1</u> kgs
B. Adverse	event or produ			
. Adverse even		roduct problem	(e.g., defects/r	nalfunctions)
check all that appl	ted to adverse event y)	disability		
death	(mm/dd/yyyy)	== -	al anomaly intervention to :	nrevent
life-threatening			nt impairment/o	
hospitalization	- initial or prolonged	other:		
Date of event 10/26	5/2000	4. Date of	05/03/2	:001
(mm/dd/yyyy) 5. Describe event or		(mm/dd/yyyy)		
Patient on	chronic low	dose ASA	started	
clopidorel	2 weeks PTA quiring hosp	for claud	dication ission	•
HCT on admi	t 16. Acute	on chron:	ic renal	
failure sec	ondary to GI	bleed.	EGD	1-
revealed 2 epinepherin	gastric ulce	ers, injed	ctea wit	n
cpinepiler.				
	ח	ECE	VED	1
	H	CCE	VLU	,
		MAY 0 7	2001	
	MF.	DWATO	JH GTI	J
	,,,,			
6. Relevant tests/la	boratory data, includi	ng dates		
Labs: 139			.7 16	
	: 10.9>16<279			
2.14 Mg1	5 FU4 5.5 F.	1 13/1.0/		
7 Other relevant h	istory, including pree	xisting medical	conditions	
(e.g., allergies, race,	, pregnancy, smoking a	nd alcohol use, h	epatic/renal dy	
PMH: 1. C	RI 2. HTN s olled 4. CO	ec to RAS	3. DM	
6. hx/o G	I bleed 7.	hx/o nose	bleeds	last
one 2 mont	hs ago requi	ring pack	ing at E	ER.
8. PVD 9	. HITT: ? ve openia 10.	rsus drug Accites:	induced	d 12/99
CITTOMBOCYC	openia io.	MOCTCED:	cupped.	,
		V. Tor		
		WATCH F ishers , Lane	or FA) 1-8	(to: 00-FDA-0178
ر السارات ا	May Rocks	ville, MD 20852		

	Trans.			
A. Patient information		C. Suspect me	edication(s)	
Patient identifier 2. Age at time 3. S	ex 4. Weight	1. Name (Product Name Clopidogrel	ne) (Labeled Strength)	(f/ffr/Labeler)
of event: 72 Years	femalelbs	#1 Clopidogrel	/75mg	/
0 -	or	#2 ASA	/81mg	
In confidence of birth:	male 61 kgs		/ 12 Thereni	detue (funka vuo civo duration)
B. Adverse event or product problem		2. Dose/Frequency/Rou	ite used 3. I nerapy	dates (Funknown, give duration) To (or best estimate)
	defects/malfunctions)	#1 75mg /qD	Oral #1 09/28,	/2001 - 10/28/2001
Outcomes attributed to adverse event Product problem (e.g.	, delicos manarios sy	81mg /qD	/Oral #2 03/26	/2001 - 10/28/2001
(check all that apply)	İ	#2		
death congenital and	· 1	4. Diagnosis for use (s	eparate indications with commas)	stopped or dose reduced
death congenital and required interv	vention to prevent pairment/damage	""		#1 ves no doesr
	pairmentoamage	#2 ASHD		
hospitalization – initial or prolonged other:		6. Lot # (if known)	7. Exp. date (if known	#2 yes no does no apply
Date of 4. Date of	/02/2001	#1	#1	8. Event reappeared after
event 10/26/2000 this report 05 (mm/dd/yyyy)	,/03/2001			reintroduction
Describe event or problem		#2	#2	#1 yes no does no apply
Patient on chronic low dose ASA st	arted	9. NDC # (for product pr		
clopidorel 2 weeks PTA for claudic	ation.	<u> </u>		#2 yes no does i
GI bleed requiring hospital admiss HCT on admit 16. Acute on chronic	renal	10. Concomitant medi-	cal products and therapy date	s (exclude treatment of event)
failure secondary to GI bleed. EGD				
revealed 2 gastric ulcers, injecte	d with			
epinepherine.	j			
		D. Suspect m	edical device	
		1. Brand name		
		2. Type of device		
		3. Manufacturer name	& address	4. Operator of device
RECEIV	FI) I			hea th professiona
ILCLIV				lay user/patient
MAY 0 7 20	nn1			other:
MEDWATCH				
MEDWALOR		6.		5. Expirat on date (mm/dd/y/yy)
		1 -		
Relevant tests/laboratory data, including dates				7 If implement all pive date
Labs: 139 106 79 Glu 164 4.7	16	catalog #		(mni/dd/y; yy)
7.2 CBC: 10.9>16<279 MCV 89.5	ICa	serial #		
2.14 Mg1.5 P04 5.3 PT 13/1.0/44				8. If explanted, give dat
				(mr 1/dd/y /yy)
		other#		
		9. Device available for	`	t send device to FDA)
		yes 📋	no returned to mar	nufacturer o n(mm/dct/yyyy)
		10. Concomitant med	ical products and therapy dat	es (exclude treatment of event)
7. Other relevant history, including preexisting medical cond	altions			
(e.g., allergies, race, pregnancy, smoking and alcohol use, hepati	3. DM -			
	Pulm HTN:		(see confidentiality see	ction on back)
2.11.		1. Name	phone #	
diet controlled 4. COPD 5. CHF/16. hx/o GI bleed 7. hx/o noseble	eeds last	Pha	armD	
diet controlled 4. COPD 5. CHF/I 6. hx/o GI bleed 7. hx/o noseble one 2 months ago requiring packing	g at ER.			
diet controlled 4. COPD 5. CHF/I 6. hx/o GI bleed 7. hx/o noseble one 2 months ago requiring packing 8. PVD 9. HITT: ? versus drug in	g at ER. nduced	VA PSHCS, 1660	S. Columbian way	
diet controlled 4. COPD 5. CHF/I 6. hx/o GI bleed 7. hx/o noseble one 2 months ago requiring packing 8. PVD 9. HITT: ? versus drug in	g at ER. nduced	VA PSHCS, 1660	Washingto	ori 98108
diet controlled 4. COPD 5. CHF/I 6. hx/o GI bleed 7. hx/o noseble one 2 months ago requiring packing 8. PVD 9. HITT: ? versus drug in	g at ER. nduced	VA PSHCS, 1660 Seattle United States	Washingt	emed.va.gov
diet controlled 4. COPD 5. CHF/I 6. hx/o GI bleed 7. hx/o noseble one 2 months ago requiring packing 8. PVD 9. HITT: ? versus drug in	g at ER. nduced	VA PSHCS, 1660 Seattle United States 2. Health professions	Washingt	emed.va.gov 4. Also reported to
diet controlled 4. COPD 5. CHF/I 6. hx/o GI bleed 7. hx/o noseble one 2 months ago requiring packing 8. PVD 9. HITT: ? versus drug in thrombocytopenia 10. Ascites: tag	g at ER. nduced pped 12/99	VA PSHCS, 1660 Seattle United States 2. Health professions	Washingt	emed .ve . gov 4. Also reported to manufacturer
diet controlled 4. COPD 5. CHF/I 6. hx/o GI bleed 7. hx/o noseble one 2 months ago requiring packing 8. PVD 9. HITT: ? versus drug in thrombocytopenia 10. Ascites: tag	g at ER. nduced pped 12/99 orFAX to:	VA PSHCS, 1660 Seattle United States 2. Health professiona yes 5. If you do not want	Washingt 3. Occupation Pharmacist your identify disclosed to	4. Also gov 4. Also gov manufacturer use facility
diet controlled 4. COPD 5. CHF/I 6. hx/o GI bleed 7. hx/o noseble one 2 months ago requiring packing 8. PVD 9. HITT: ? versus drug in thrombocytopenia 10. Ascites: tag Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-978	g at ER. nduced pped 12/99 or FAX to: 1-800-FDA-0178	VA PSHCS, 1660 Seattle United States 2. Health professiona yes 5. If you do not want	Washingt 3. Occupation Pharmacist	4. Also gov 4. Also gov 4. Also gov 1. Al
diet controlled 4. COPD 5. CHF/I 6. hx/o GI bleed 7. hx/o noseble one 2 months ago requiring packing 8. PVD 9. HITT: ? versus drug in thrombocytopenia 10. Ascites: tag Mail to: MEDWATCH 5600 Fishers Lane	g at ER. nduced pped 12/99 or FAX to: 1-800-FDA-0178	VA PSHCS, 1660 Seattle United States 2. Health professiona yes 5. If you do not want the manufacturer,	Washingthal? 3. Occupation no Pharmacist your identity disclosed to place an "X" in this box.	### 4. Also reported to ### distributor

	blance or an energy way
Microsoft NSADSS2(001010650
UF-Disa report #	
	FDA Use Onth

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¥371I	8001-5-00-01* PRODUCTS REPOR	TING PROGRE	(N	Page	of <u>3</u>			FDA U	se (Inh
					C. Suspect medication	n(s)			
A. Patient infor			. Sex	4. Weight	Late Jaire labeled streng	h & mrr/labeler, i	f known)		
Patient identifier	2. Age at time of event: 52 vr		temale	UNK15s	#1 REOPRO (2 mg	/ml sol:	ution)(ABC	(IMIMA)	i
	or event: 52 yr			unk	#2 HEPARIN SCD	TM (HEPA)	RIN SODIUM	4)	
	Date		male	UNK kgs				s – (if anknown, give denote n)	
In confidence	of birth:	e m			2. Dose, frequency & rome in	ard	5. Therapy dates from to turn test color	mare)	
	ent or product proble	Product problem	(e.g. defects/m	alfunctions)	#1 IV		#1 08/24/	00 - 08/25/00	
Adverse event					#2 IV		#2 08/24/	00 - 08/25/00	
Outcomes attributes	n in naverse event	disability			4 Diagnosis for use (indic	gien)		5. Event abated after use	
deah		congenital at	iomaly evention to preve	,,	#1 ACUTE MYCCA INFARCTION	RDIAL		stopped or dose reduce	
ife-threstering	americay/yet Og		rvention to preve npairment/camag		#2 ACUTE MYOCA	RDIAL		41 1 100 100 100	apply
- Falseitalizatio	on - Initial or protonged	other:			INFARCTION			#2 □ 301 □ no □	dosent apply
		4. Date of			6. Lot# (if known)	7. Exp	. date (if known)	S. Event reappeared after	
.Date of event ∂87	/25/00	this report	04/11/	01	"1	_		reintroduction	
enseklas/yr-		Imavda y/yT1			±2	#2		#1 🔲 500 🔲 500 🕱	locsn't apply
Describe event or p	problem	aa a awbid	act ento	lled	9. NDC# - for product pro	olems only (if kn.	ימאמ	#2 \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	doesni
in cono	eceived involventech Phase I	ilb. rando	カルエムセステ						apply
aho	al chudy compai	ring enoxa	abarii,	tion	10. Concomitant medical pr	educts and	therapy dates rexclud	de deatment of events ??/?? = 08/24/	nn
+b TMXa	and abciximab ase in subject	s with act	ite		1) ASPIRIN(A ICYLIC AC	JETYLSAL ID)			
myocardia	infarction	(AMI).			2) INSULIN(I	NSULIN)	08/2	4/00 - 08/25/0	(U
a 52-vear	r-old woman su	bject (#5	37294),						
di anta da cara ca	or specified, g-00. The sub	developed	a Gr br	eed th a				(Cont.)	
	at infarction	on 24-Aug	-uu ana	was				:Cont	
	ed to the half b and heparin	-cose inv	ase.		G. All manufacture 1. Contact office - name/ad		fring site for devices)	2 Phone numbe	: Γ
$-2 \le 3 u \alpha = 0.0$	n leiv hours a	end 40 min	uces all	er	Carrocar T	nc.	-	\$10-889-4	1 535
the study	y drugs were a	administer Thleed	ed, the The abci	ximab	ll 200 Great Va	allev Pa	rkway	3. Report source	
i m Euro i on	wae darreased	nv one-c	arr upse	. 4344	Malvern PA	L9300-13	J,	(check all that	. apply)
0 = blacc	25.5 seconds. occurred and	the nebai	ili anu		(Informing	Unit)		x foreign	
	L influerance We	ere discon	rirued.	The				x study	
	was hemodynami with volume re	entacement	andar)130u				literature	e
- E	ion. An upper by was performs	~ MASEYOUT	restina.	L				consum	er
	Lacuare distai	esophagi	.TlS. A					health proviessa	ional
	angiogram was 00 and showed :	s pertorme	ea on	ase.	4. Date received by manuf		(A-NDA#		rility
			10	Cont.)	C4/05/01		IND#	compar	ay intistrye
6. Relevant tests/la	aboratory data. including	dates			6. If IND, protocol#		PLA#		
U.ab dat	ca cont.				N2139G/1123.	10	pre-1938	yes distribu	itor
1					7. Type of report		OTC	Otter:	
					(check all that apply)	. [product	yes	
					5-day x 15-day	·	3. Adverse event te		
					10-day period	ıc	1) OESOPH 2) CORONA	AGITIS RY ARTERY	
					x initial follow	-up#	DISORD 3) GI HAE	ER	
				Cont.) GI HA≃	MORNIMOL	
7. Other relevant	history, including preexisting king and alcohol use, hepatic/re	medical conditions enal dysfunction, etc.		illergies, race.	9. Mfr. report number NSADSS2001010650				
Obesity									
*** -	ncion diabete	es mellitu	S,		E. Initial reporte	r			
hyperche infarct	olesterolemia	and PICA	WI CITCUIC		Name, address & pho	ne#		1,3,3	
					Mr James N. Genetech,	Tr.C		1263	
					1 DNA Way	Prancisc	o, CA 9408	80-49900 5 700	
1 5	11四世世代之後	\			South San		, 3 2.0		
1 // //	With the Land of the Control	 ' +							
1	Annual Control				2. Health professional?	3 Ocei	pation	4. Initial reporter ab sent report to FD:	SO A
<u>ا</u> ال	ALIN / 6 Autom	nission of a report duission that medical p	es not constitute ersonnel, user fac	an ility.	k yes □ n	Pha	rmacis	yes []	no 🔽 on
	distri	ibutor, manufacture	r or product caus	ed or	, , , , , , , , , , , , , , , , , , ,				
3500A Facsing c	contr	ributed to the event.					الأطيد	1 9 2001	
	The second of th						mi II	T & COD!	

Centocor, Inc.
r use by user-facilities,
rs and manufacturers for

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Hrrapin 4 NSADSS2001010650	ł
. F/Dist report #	
FIX to (Init	

RE FOR MEDICAL INDUCES	Page	or	
A. Patient information		C. Suspect medication(s) 1. Name (give labeled strength & mir/labeler, if knew	n)
Patient identifier 2. Age at time	3. Sex 4. Weight	1. Name (give labeled strength & manufacture, it can a	·· I
of event:	female		
Date	malekes	#4	
In considerace of birth:		2 Indicate approximation	Phermpy dates — (if unknown, give datation) number of bot estimate
B. Adverse event or product	Product problem (e.g., defects/malfurctions)		08/24/00 - 08/24/00
Adverse event and/or	Product problem (c.g., detection)	#4 #4 #4	
Outcomes attributed to adverse event (check all that apoly)	disability	1. Dinamois for use (indication)	5. Event abated after use
dearlt	congenital anomaly	#3 ACUTE MYOCARDIAL	stopped or dose reduced
Interthreatening	required intervention to prevent permanent impairment/damage	INFARCTION	#3 yes no desn't
inescalalization - mittal or professed	''		#4 yes no doesn't
		6 Lot # (if known) 7 Exp. date #3	(if known) apply 8. Event reappeared after
5. Date of event	4. Date of this report	#3	reintroduction
i gavda y'y r.	(my/da)/yrl	#4 #4	#3 yes no desn't
5. Describe event or problem		NDC # - for product problems only of known)	#4 ves no doesn't
			apply apply
		10. Conconitant medical products and therap	y dates (exclude treatment of event)
6 Relevant tests/laboratory data, it	neluding dates	4. Date received by manufacturer (5)(A)ND/(ImAdas/yr) 6. If IND, protocol # PLA	company representative distributor yes sthere
		5-day	verse event term(s)
7. Other relevant history, including pre- pregnancy, smoking and alcohol use.	exasting medical conditions (e.g., allergies, race, lepane/regal dysfunction, etc.)	9. Mfr. report number	
		E. Initial reporter 1. Name, address & phone #	DSS
			₩6¥ 8 % 20 01
	Submission of a report does not constitute an admission that medical personnel, user facility,	2. Health professional? 3 Occupation	4. Initial reporter also sent report to FDA set set set set set set set set set set
3500A Facs male	distributor, manufacturer or product caused or contributed to the event.		APR 1 9 2001

Mfr. report # : NSADSS2001010650 Page 3 of 3

Date of this report: 04/11/01

B. Adverse event or product problem

B.5 Describe event or problem (Cont...)

The event resolved with no new episodes of GI bleed occurring since the discontinuation of the study drugs.

The investigator considers the event possibly related to study therapy.

B.6 Relevant tests/laboratory data, including dates (Cont...)

Lab Result:

Lab Res	mi :		rest result	Normal value
Sl.No.	Test date	Test name		
	58/05/30	ACTIVATED PARTIAL THROMBOPLASTIN	25.5 sec	(second)
<u>-</u>	33, 23	TIME	UNK	
2	58 3 1 /11	upper SI// distal esophagitis UNX Angiogram// multi-vessel diseas	ONK.	

C10. Concomitant medical products

Seq No.
Concomitant Medical Product
Dose, frequency & route used
Diagnosis for use(indication)

Seq No. Concomitant Medical Product Dose, frequency & route used Diagnosis for use(indication)

: 1 : ASPIRIN(ACETYLSALICYLIC ACID)

:1) unknown : _) UNKNOWN

: 2

: INSULIN(INSULIN)
: 1) unknown
: 1) UNKNOWN





	# frcqer 11M	A109931	
"+" indicates	UF/Dist report	ŧ	
			FDA Use ()nlv

Approved by FDA on 12/02/93

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 6

A. Patient Ir	nformation				C. Suspec	ct med	cation(s)			
.Patient Identifier	1. Name (give labeled strength & mfr/labeler, if known)										
	of event:	72 YRS		126.0 lbs	Olbs #1 NORVASC TABLETS						
in confidence	or — Date of Birth:		Female Male	or kgs	#2 TROGLITAZONE Cont.						
B. Adverse	event or pro	duct pro	blem		2. Dose, freque			· -	from/	nknown, give duration) /to (or best estima es)	
					# 1 5.00 MG TOTA	L:DAILY:ORAL		# 1 03/1	3/00 - UN	IKNOWN	
Adverse even			(e.g. defects/m	alfunctions)	# 2 600.00 MG TO	TAL		# 2 03/-	-/ 97 - 03/-		
(Check all that apply		disabilit disabilit	ry		4. Diagnosis fo	ruse (inc	lications)			t abated after t se d or dose reduced	
death	1	11	ital anomaly		# 1 UNCONTROLLED	HYPERTENSION	l 		1	doe sn't	
life-threatening	iay/yr)	required perman	d intervention to ent impairment	damage	# 2 DIABETES MELLITUS # 1 yes X no apply						
→ hospitalization	- initial or prolonged	other:			6. Lot # (if know	wn)					
3. Date of		4. Date of this repo	ort 05/08/	01	#1 UNKNOWN		#1 UNKNO	WN		it reappeared a ter	
event 06/ (morday/yr)	//00	(mo/day/yr			#2 UNKNOWN		#2 UNKNO	WN	reintroduction		
5. Describe event	or problem	<u> </u>			9. NDC # - for p	product pro	blems only	(if known)	#1 - v	doesn't es [7] no [X] apoly	
MEDICAL RECORI	S RECEIVED FRO	OTTA NA MC	RNEY INDIC	ATED THAT	9. NDC # - 101 }	blodder pro	Diorns only	(11.10.11.)	<u> </u>	doesn't	
A 72 YEAR OLD	FEMALE WITH A	HISTORY O	F DIABETES	1	N/A				# 2 🔲 y	res 🗌 no 🔀 apoly	
MYOCARDIAL IN	FARCTION, RIGHT	T CORONARY	ARTERY DI	SEASE,	10.Concomita	nt medical	products	and therapy da	ates exclu	ude treatment of event)	
CHRONIC RENAL	FAILURE, AND	fatigue wa	S PRESCRIB	ED	GLUCOTROL		-		UNKNO	OWN PRESENT OWN PRESENT	
UVDERTENSION 1	DIPINE) 5MG DA FROM 13MAR00 U	NTIL AN UN	SPECIFIED	DATE.	CLARITIN PRINIVIL				UNKNO	WN - PRESENT	
THE PATIENT A	LSO TOOK REZUL	IN (TROGLI	TAZONE) 60	OMG DAILY	XANAX PREMARIN				UNKNO	OWN - PRESENT	
POP DIARETES	MELLITUS FROM	MAR97 UNTI	L MAROO, C	CUMADIN	ARTHROTEC				UNKNO		
(WARFARIN SOD)	IUM) IN OCTOO AXIS AND ASPIR	FOR DEEP V IN IN MAR(O FOR AN U	NKNOWN	G. All ma	nufact	urers				
INDICATION, I	N ADDITION TO	OTHER CONC	COMITANT					mfring site for	devices	2. Phone number	
MEDICATIONS.	E PATIENT EXPE	DIENCED A	FLUSHED FI	EELING	1. Contact office - name/address (& mfring site for devices) 2. Phone number 212-573-3129 PFIZER REGULATORY SAFETY PFIZER PHARMACEUTICALS 3. Percept sources						
WHICH WAS THO	UGHT TO BE SEC	ONDARY TO	PLENDIL								
(PELODIPINE).	FELODIPINE TH	ERAPY WAS	DISCONTING	JED AND	235 EAST 42 STREET NEW YORK, N.Y. 10017 U.S.A [] foreign				3. Report source		
NORVASC (AMLO	DIPINE) THERAP	WAS STAI	ONTINUED.	ON							
28JUN00. THE	PATIENT SAW HE	R PHYSICIA	AN FOR SWE	LLING OF							
HER FEET AND	PAIN IN BOTH I LING ASLEEP EA	EGS WHEN I	WALKING. :	SHE HAD SICIAN					ĺ	study	
DESCRIBED AS	SOMNOLENCE. I	HE PHYSIC	IAN DETERM	INED THE						literature	
PATIENT WAS S	UFFERING FROM	PERIPHERA	L VASCULAR RTERIOGRAM	DISEASE		14		5.		consumer consumer	
WITH CLAUDICA	TION. ON USJU	JLUU, AN A	KIEKIOGRAM	MAS	(moldayArt)				health profess ona		
				+	1 '	2/27/01		NÓA# NOA#	19-787	user facility	
6 Pelevant teste	/laboratory data,	including dates			6. If IND, prote			PLA#		company representative	
	inaction of duta,	including dates	•		1	JJ01 #		pre-1938	yes	distributor	
PASTING BLOOD SUG	3AR: 164				N/A			- -		otner	
HEMOGLOBIN A1C: 7					7. Type of report product product				-		
					(check all the	at app y)		8. Adverse	event to	erm(s)	
13MAR00: BLOOD PRESSURE 14	40/40				☐ 5-day	☆ 15-day		BOMNOLENCE			
PULSE: 72	· - -				☐ 10-Day	perjodic		PURPURA EDEMA			
REIGHT: 63 INCHES	5				+ M initial follow-up # ANNORMAL STOOLS						
	(Links, 1, 1, 1), din a	proprieting	medical con		'`` •	,	「 " <u></u>	ASTHENIA GASTROINTE		emorrhage	
/. Other relevant	history,including pregnancy, smoking	& alcohol use	hepatic/renal di	rsfunction,etc.)	9. Mfr. report	number		COAGULATIO			
(e.g., allergies, race,	, pregnancy, amorning		· · · · · · · · · · · · · · · · · · ·		A109931			LAB TEST A	BNORMAL		
- MAR99					E leitie	Ironer	ter				
NICOTINE CONSUMP	TION:				E. Initia					DCC-	
- SINCE 1920 HYPERTENSION:					1. Name , ad	aress & pr	ione #			DSS	
- SINCE 1992								HITE	.	NC 2	
NAUSEA: - 02DEC96								UITE	r Mi∆	Y i 4 2001	
VOMITING:					+ Tel.						
	Submission of a	report does n	ot constitute a	n admission	2. Health profe		3. Occupat		4. Initia	i reporter also report to FDA	
(FIL) // /\	that medical pers	ionnel, user fa	acility, distribu	nor, manuta-	☐ yes	🔀 no	PARALEGAL	-		es Flno 1∑tun:	



cturer or product caused or contributed to the event.

Individual	Safety R	eport
Individual	I 188 3 I 1881 I 1881 I 1881 I 1881 I 1881 I	
/ 1886 600 1884 WAY AND 188	P (NGAP ANT KATAN APPRANT	
77777765577	00-02 ≠	

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	Approves by FDA on 10/02/93
	Mfr report # # # # # # # # # # # # # # # # # # #
	UF/Dist report ≠
Page 2 of 6	FDA Use (Inly

<u>z</u> 01 <u>-</u>	Ĺ	,				FL	A US	se Chily
C. Suspect me	edication	(s)						
1. Name (give labeled st			iown)					
#3 WARFARIN SODIUM								
# 4 ASPIRIN								
2. Dose, frequency & # 3 5.00 MG TOTAL:DAILY:		3.The # 3	• •		S(if unk from/to RESEN	(cr bes	ive d	luration ima es)
# 4 UNKNOWN		# 4	03/-/	00 - L	NKNOW	'n		
4. Diagnosis for use # 3 DVT PROPHYLAXIS	(indications)				Event ped o			uced
# 4 INDICATION UNKNOWN				# 3	🗶 yes	[] no		doesn'i apply
6. Lot # (if known) #3 UNKNOWN	7. Exp. da #3 UNKN	`	nown)		UNI ☐ yes Event			dousn' arply dafte
# 4 UNKNOWN	#4 UNK	IOWN		-	reintro	KNOM	on V	do-;sn
					UNI UNI Ves	KNOW	4	arply doesn'

DSS

MAY 1 4 200



Pfizer Regulatory Safety, Pfizer Pharmaceuticals - Mfr. report # A109931

B5. EVENT DESCRIPTION - Continued

PERFORMED AND REVEALED A 75% SIGNIFICANT STENOSIS OF THE RIGHT EXTERNAL ILIAC. ON 25SEP00, THE PATIENT SAW HER PHYSICIAN FOR BRUISING, LEG EDEMA AND FATIGUE. THE LEG EDEMA WAS THOUGHT TO BE SECONDARY TO AMLODIPINE. AMLODIPINE THERAPY WAS DISCONTINUED. IN JUN00 THE PATIENT HAD AN ELEVATED THYROID STIMULATING HORMONE (TSH) LEVEL OF 5.52. ON 11JUL00 THE PATIENT HAD A STENT PLACED TO THE RIGHT ILEAC ARTERY. AS OF 11JUL00 THE PATIENT CONTINUED TO COMPLAIN OF SWOLLEN FEET AND LEGS HOWEVER SHE DID NOT HAVE ANY CLAUDICATION AFTER HER STENT PLACEMENT. ECCHYMOSIS WAS NOTED ON THE PATIENT'S RIGHT ARM DURING THE PHYSICAL EXAM. ON 090CT00, THE PATIENT WENT TO THE EMERGENCY ROOM FOR RIGHT LOWER EXTREMITY PAIN AND SWELLING AND WAS ADMITTED TO THE HOSPITAL. SHE WAS PRESUMED TO HAVE DEEP VEIN THROMBOSIS AND WAS STARTED ON HEPARIN. DOPPLER SCANS WERE NEGATIVE FOR DEEP VEIN THROMBOSIS, BUT ON 100CT00,

THE PATIENT'S VENOGRAM WAS POSITIVE FOR DEEP VEIN THROMBOSIS. SHE WAS GIVEN COUMADIN (WARFARIN SODIUM) AS A PULMONARY EMBOLUS PROPHYLAXIS AND DEMEROL (PETHIDINE HYDROCHLORIDE) FOR HER PAIN. HER HEMOGLOBIN AND HEMATACRIT AT THAT TIME WERE 11.2 AND 32.5 RESPECTIVELY. THE PATIENT WAS DISCHARGED ON AN UNKNOWN DATE. ON 120CT00 SHE WAS SWITCHED FROM HEPARIN TO LOVENOX AND CONTINUED ON HER COUMADIN, BY 170CT00 THE PATIENT FELT BETTER, HER LEG PAIN HAD IMPROVED AND HER PT AND INR WERE 19.0 AND 2.48 RESPECTIVELY.ON 23NOV00, THE PATIENT AGAIN WENT TO THE EMERGENCY ROOM WITH SWELLING OF THE RIGHT LEG AND UPPER EXTREMITY. IN THE EMERGENCY ROOM, SHE WAS NOTED TO BE MARKEDLY ANEMIC AND SUFFERING FROM HYPERPROTHROMBINEMIA AND COAGULOPATHY, WHICH WERE THOUGHT TO BE SECONDARY TO WARFARIN THERAPY. THE PATIENT'S HEMOGLOBIN AND HEMOTACRIT WERE 7.4 AND 23.4 RESPECTIVELY. THE PATIENT'S WARFARIN DOSE WAS DECREASED AND HER PLAVIX (CLOPIDOGREL) AND VIOXX (ROFECOXIB) WERE HELD. SHE WAS ADMITTED TO THE HOSPITAL FOR FURTHER OBSERVATION AND TREATMENT. THE PATIENT REPORTED EXPERIENCING BLACK STOOLS FOR TWO TO THREE WEEKS. ON 28NOVOO, AN ESOPHAGOGASTRODUODENOSCOPY WAS PERFORMED AND REVEALED HIATAL HERNIA AND

ANTRAL GASTRITIS. ON 29NOVOO, A TOTAL COLONOSCOPY WAS ALSO PERFORMED AND SHOWED INTERNAL HEMORRHOIDS WITH NORMAL EXAMINATION OF CECUM AND NO OBVIOUS CHRONIC PATHOLOGY TO EXPLAIN ANEMIA. PATIENT ALSO EXPERIENCED A GASTROINTESTINAL BLEED. TREATMENT WITH VITAMIN K (PHYTOMENADIONE) RESOLVED THE PATIENT'S COAGULOPATHY. ON 04DEC00, THE PATIENT WAS DISCHARGED IN IMPROVED AND STABLE CONDITION. ON 11DEC00 SINCE SHE CONTINUED TO HAVE EDEMA OF THE LOWER EXTREMITY AND COMPLAINED OF "VOMITING A LITTLE BLOOD" HER COUMADIN WAS DECREASED TO 5 MG 1/2 TABLET. VIOXX AND HYDROCHLOROTHIAZIDE WERE ALSO DISCONTINUED DUE TO HER GI BLEEDING. ON 19DEC00 THE PATIENT PRESENTED TO HER PHYSICIAN'S OFFICE COMPLAINING OF LEFT THIGH PAIN AND TENDERNESS. AS A RESULT, THE PATIENT WAS ADMITTED TO THE HOSPITAL FOR TREATMENT OF A DVT ON AN UNKNOWN DATE. ON 15JAN01 SHE CONTINUED TO COMPLAIN OF LEFT CALF SORENESS AND HER PT/INR " HAD BEEN FLUCTUATING A LOT." ON 11JAN01 HER PT AND INR WERE 20.3 AND 2.82 RESPECTIVELY. THE PATIENT WAS INSTRUCTED TO INCREASE HER COUMADIN TO 5 MG DAILY. ON 18JAN01 THE PATIENT CONTINUED TO COMPLAIN OF PAIN IN HER LEFT CALF, AS A RESULT THE PATIENT WAS ADMITTED TO THE HOSPITAL FOR TREATMENT OF A DVT ON AN UNKNOWN DATE. NO FURTHER INFORMATION WAS AVAILABLE AT THE TIME OF THIS REPORT.

B6. RELEVANT TESTS/LAB. DATA - Continued

WEIGHT: 126 POUNDS

HEMOGLOBIN A1C: 6.9 (NORMAL 4.5-5.7)

05JUL00:

PHYSICAL EXAM:

EXTREMITIES): 1+ EDEMA BILATERALLY. POSITIVE RIGHT FEMORAL BRUIT. DECREASED PEDAL PULSES IN THE RIGHT LOWER

ARTERIOGRAM-75 % SIGNIFICANT STENOSIS OF THE RIGHT EXTERNAL ILIAC ARTERY THROMBOSIS INVOLVING THE RIGHT CALF.

29JUN00:

NORMAL RANGE (4.00-5.00) RBC (MIL/UL): 3.77

HEMOGLOBIN (G/DL): 10.9 NORMAL RANGE (12.0-16.0)

HEMATOCRIT (%): 33.9 NORMAL RANGE (36.0-48-0) NORMAL137-145 SODIUM (MMOL/L):134

NORMAL (0.46-5.0) TSH (MU/ML): 5.52

NORMAL RANGE LESS THAN 7 HEMOGLOBIN A1C: 6.7

31JUL00:

NORMAL (3.5-5.5) ALBUMIN: 3.4

NORMAL (20-32) CARBON DIOXIDE: 19

HEMOGLOBIN A1C: 6.7

ASACTOR:

HEMOGLOBIN: 11.2

HEMATOCRIT: 32.5

VENOUS DOPPLER AND VENOUS IMAGING: NO EVIDENCE OF DEEP VEIN THROMBOSIS

RED CELL WHOLE BODY VENOGRAM: FINDING SUGGESTIVE OF EVIDENCE OF DEEP VEIN THROMBOSIS

MAY . 4 /001

01NOV00: PT 20.3

MAY 1 4 300.



PROTHROMBIN TIME: 13.2

INR: 1.22

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Pfizer Regulatory Safety, Pfizer Pharmaceuticals - Mfr. report # A109931
INR: 2.82
06NOV00:
RBC (MIL/UL): 2.75
                        NORMAL RANGE (4.0-5.0)
HEMOGLOBIN (G/DL):7.7 NORMAL RANGE (12.-16.0)
                       NORMAL RANGE: (36.0-48.0)
HEMATOCRIT (%): 25.2
PROTHROMBIN TIME
(PT IN SEC): 24.1
                       NORMAL 11.1-12.7
                        NORMAL RANGE: (2.0-3.5)
INR: 3.93
24NOV00:
HEMOGLOBIN: 7.4
HEMATOCRIT: 23.4
25NOV00:
CHEST X-RAY - NO ACUTE CARDIOPULMONARY PROCESS.
PROTHROMBIN TIME (SEC): > 45 SECONDS
TOTAL FIBEROPTIC COLONOSCOPY: REVEALED TWO INTERNAL HEMORRHOIDS AT 30'CLOCK AND 11 0'CLOCK.
27NOV00:
RIGHT FOOT X-RAY: FORESHORTENING OF THE 5TH METATARSAL BONE DISTALLY.
30NOV00: NON-SPECIFIC CALCIFICATIONS ARE PRESENT IN THE PELVIC REGION, MOSTLY ON THE LEFT SIDE. THERE IS A
VASCULAR STENT TO THE RIGHT ILIAC REGION.
01DEC00:
CHEMISTRY:
SODIUM: 138
POTASSIUM: 3.5
CHLORIDE: 103
CO2: 25
GLUCOSE: 214
BUN: 10
CREATININE: .6
PHOSPHOROUS
11DEC00:
PROTHROMBIN TIME:
    PATIENT TIME: 80.2 NORMAL RANGE (9.4-12.5)
                            NORMAL RANGE (2.0-3.5)
INR: 6.7
HEMOGLOBIN (G/DL): 10.9
HEMATOCRIT (%): 31.6
RBC: 3.62
15DEC00:
                                NORMAL RANGE (11.1-12.7)
PROTHROMBIN TIME (SEC): 14.8
                                NORMAL RANGE: 2.0-3.5
INR: 1.53
18DEC00:
PROTHROMBIN TIME (PT): 25.3 NORMAL RANGE (11.1-12.7)
INR: 4.32
                                NORMAL RANGE (2.0-3.5)
28DEC00:
PT: 18.4
INR: 2.33
11JAN01:
PROTHROMBIN TIME: 20.3
INR: 2.82
01FEB01:
```

NORMAL RANGE (11.1-12.7)

NORMAL RANGE (2.0-3.5)



Pfizer Regulatory Safety, Pfizer Pharmaceuticals - Mfr. report # A109931

15FEB01

PROTHROMBIN TIME: 13.4

INR: 1.26

B7. OTHER RELEVANT HISTORY - Continued

- 02DEC96

ABDOMINAL PAIN:

- 02DEC96

CHEST PAIN:

03DEC96

BACK PAIN

- 03DEC96

HIATAL HERNIA:

- 04DEC96

ACUTE EROSIVE GASTRITIS:

- 04DEC96

SUPERFICIAL DUODENAL ULCERS:

- 04DEC96

RENAL CYST:

- 04DEC96

INTERNAL HEMORRHOIDS:

- 24JAN97

COLON POLYP:

- 24JAN97

PROBABLE ADHESIONS:

- 24JAN97

ALLERGY TO PENICILLIN:

- 24JAN97

ALLERGY TO MYCINS:

- 24JAN97

CONSTIPATION:

- 24JAN97

HYSTERECTOMY: - 24JAN97

ESOPHAGITIS:

- 24JAN97

ELEVATED CARDIAC ENZYMES:

- MAR99

ACUTE NON-WAVE MYOCARDIAL INFARCTION

CARDIAC CATHETERIZATION:

- 17MAR99

UNSTABLE ANGINA:

MILD NONOBSTRUCTIVE CORONARY ARTERY DIS:

- 17MAR99

SMALL BOWEL OBSTRUCTION

WEIGHT LOSS:

- 24JAN97

CHRONIC RENAL FAILURE

SORE BUTTOCKS:

- 16NOV99 - FURNCLE NOTED ON LEFT BUTTOCK

GOUT:

LEFT ELBOW SWELLING

FLUSHED FEELING

HYSTERECTOMY

TUBAL LIGATION

CONGESTIVE HEART FAILURE (CHF)

C10. CONCOMITANT MEDICAL PRODUCTS - Continued

VERAPAMIL.

PRANDIN

HCTZ

PLENDIL

UNKNOWN - PRESENT UNKNOWN - PRESENT

UNKNOWN

UNKNOWN - PRESENT

G8. ADVERSE EVENT TERMS - Continued

MAY 3 + 2001



Pfizer Regulatory Safety, Pfizer Pharmaceuticals - Mfr. report # A109931

PERIPHERAL VASCULAR DISORDER
DEEP THROMBOPHLEBITIS

DSS

MAY 1 4 2001

30 April 2001

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

.1.

For use by user-facilities, distributors and manufacturers for MANDATORY reporting Pharmacia & Upjohn, Inc.

Periodic Page 166 - 1

	Relays International, li FDA Facsimile Approvat: 30-JUN-19							
Mir report #	2001039641US							
	FD/\ Use Only							

A. Patient info	rmation					ect medicatio				
1. Patient Idenfifier	2. Age at time		3. Sex	4. Weight		give labeled stre				
UNK	of event:	UNK	female	UNK tos		EBREX(CELE				
in confidence	Date of birth:	UNK	x male	UNK_kgs				ETYL (continue	ed) is (if unknown, çive duration	
	ent or product	nroblem			2. Dose, f	requency & route	e naed	bonds (ar best extra		
		Product proble	m (e.a. defe	cts/malfunctions)	#1. 200	mg, bid, oral		#1. UNK		
1. X Adverse eve			iii (o.y., deic	Classication	# 2. low,			#2. UNK		
	buted to adverse e	event Gisability	,		_	sis for use (Indic		5. Eve	nt abated after use oped or dose recuced	
(check all that	apply)]		al stenosis NOS		#1 <u></u>	yes no spoly	
death	(markey/yr)		ial anomaly Intervention	to prevent	6. Lot # (i	al stenosis NOS (known) 7.1	Exp. date (if k	nown) #2.	Ves no coesn't	
life-threaten	ing	permane	ent Impairme	nt/damage	# 1. UNI		ı. UNK		UNK	
hospitalizati	ion - initial or prolo	nged 🗌 other: _			# 2. UNI	K #1	2. UNK		nt reappeared after froduction	
3. Date		4. Date of				- for product pro	blems only (if	known) #1.	yes no apply	
of event	UNK	this report	04/	24/2001				#2.	yes no supply	
5. Describe even					10 Coppe	n Isolinam transfer	roducts and f	herany dates lexi	clude treatment of event)	
gastrointesti	nal bleeding[Ga	strointestinal ha	emorrhage	NOS]	NI			···	·	
				ļ						
Case Descrip	puon: Spontancous R	coort								
Į	•				G. All M	lanufacturers				
On 08-JAN-	2001 a physicia	n called to inqui	re if it was	safe for a	1.Contact office - name/address (& mfring site for devines) 2. Phone number Pharmacia					
patient with	a recent history	of gastrointestir in reports a patie	na biccount	to restant	Cheryl Watton, M.D. (616)833-877					
(celecoxib)	c. This physicia 200 mg twice da	ally and low dos	e aspirin fo	r spinal	Safety Officer 3. Report source (check all that soul					
stenosis and	inflammation d	leveloped gastro	intestinal b	leeding. The		rtage Road			(check all that apply)	
		ointestinal bleed	ling may bo	due to the low	Kalama	zoo, MI 49001	UNITED ST	TATES	loreign	
dose aspirin.	•				1				study	
1									☐ literature	
Ì						ceived by	5.			
					(mordayiye)		(A)NDA	# 20998	professional	
						08/2001	IND#		user fer illity	
					6. IT INO,	protocol #	PLA	•	Compary representative	
	s/laboratory data, l	ncluding dates			7. Type o	f record	pre-1	938 🗌 yes	distribu or	
NI NI						ali ihat apply)	отс	. 🗆 1800 %	other:	
					5-day	☐ 15-day	produ			
					10-day	y Y periodic	1	se event term(s) testinal hacmort	PON soed	
					x initial	tollow-up #	Castron	resmin intelligit	IME 1100	
1					9. Mfr. re	port number				
7 Other relevan	nt history, including	preexisting medic	al conditions	(e.g. allergies,	200103	19641US	İ			
race, pregnan	icy, smoking and al	icohol use, nepatici	renal dyszuni	tion, etc.)						
#1 concurre	ent condition, S	pinal stenosis N	OS S		1	al reporter		obone é		
#2 concurre	ent condition, in	nflammation NO	13		1. Name	& address M.D		phone #		
F								am 4 m CC		
]		UNITED :	STATES		
				adminutes that					The Management of the Control of the	
	Submission of medical person	f a report does not onnel, user facility,	constitute an distributor, m	anufacturer or	2. Healt	h professional ?	3. Occupation physician		4. Initial reporter also sent report to FDA	
		ed or contributed to			yes	∏no	l'intaician		yes no Nunk	

x yes no



Experience Report (continued)

30 April 2001

mission of a report does not constitute idmission that medical personnel, user ity, distributor, manufacturer or product caused or contributed to the event.

onstitute nel user	Pharmacia & Jpjohn, Inc. U.S. DEPARTMENT OF HEALTH AND FUMAN SERVICES Public Health Service - Fond and Lyng Afministration
nel, user r product vent.	Mir report 4 20(1) 039641 US
	FDA Use Cnly

	Periodic Page 166 - 2	
1	Additional Information	
	C1. Name (cont.) Suspect Medication #1: CELEBREX(CELECOXIB) capsule Suspect Medication #2: ACETYL SALICYLIC ACID(ACETYL SALICYLIC ACID)	

FAX:

FAGE 1

Регт Афр	eved: OMB No. 9510-0291 Express 12/31/16 See OMB alatament on reverse	
TIA Use Only	K Ped	
Triage unit	10000	١

		TARY reporting	She OMB statement on rever FDA Use Only K Pad
VICI	OVVAIUM events and p	essionals of adverse roduct problems	Tringo unit sequence 9 143404
In confidence B. Adverse Courcer as an other all that bosoitaliz 3. Date of	tinformation tiler 2. Age at time of event: S 7 Sex Sex Sex Sex Sex Sex Sex Sex Sex Sex	C. Suspect medication(s 1. Name (give labeled strength & mfr/label 1. V TOX X 12. ASA E.C. 2. Dose, frequency & route used 11. 12.5 mg of 12. 325 mg of 4. Diagnosis for use (indication) 11. 7	
Admirth assisted	b/14/01 this report 5/15/01 Indexpress to lospetal from a cl lway facility E. gross bleeding	#2 9. NDC # (for product problems only) 10. Concomitant medical products and to	reintroduction #1 yes nc doesn #2 yes nc doesn #2 pes nc

Brand name	ect medical device		
2. Type of dev	ice		
3. Menufacture	r name & address	4.	Operator of device health professions lay user/patient other:
6. model #	RECEIV	ED	Expiration date (mohterly)
catalog #	MAY 1 6 ?	001 '.	lf Implanted, give da क्षान्यकार्पः)
lot#	MEDWATCH	1010	if explanted, give da (madeyry)
9. Device avail.	(l) for evaluation?	Do not send to FD. to manufacturer on	A)

6. Relevant tests/laboratory data, including dates EDG- & bratal hamra, severe ulcerative esophagetis - duoclanal ulcer probably 20 to NSAIDS. Hct 24 on 3/14/01

Other relevant history, including preexisting medical conditions (e.g., allergies, race, prignancy, smoking and alcohol use, hapatic/renal dysfunction, etc.)

NOT KNOWN

MAY 15 2001

C.	7u	143404
A	Mell to:	MEDWATCH 5600 Fishers Lane

of FAX to: 1-800-FDA-0178 Rockville, MD 20852-9787

2. Health professional? yes 🔲 no

ı	J. Occupation
1	-1
1	Pharmacist
J	11 11 11 11 11 11
u	nie identity disclosed to

4. Also reported to manulacturer user facility

If you do NOT want the manufacturer, place an "X" in this box.



VOLUNTARY reporting ealth professionals of adverse ents and product problems

Form A	pproved: CIGO No., 0010-0001 Expi ea: 11/00 See CIGO vialement an rever
DA Use Ordy	
Yiago unii vquaneo i	143439

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM C. Suspect medication(s) A. Patient information 1. Name (give labeled strength & mfr/tabeler, if known) 4. Weight . Patient identifier 2. Age at time of event: Broke Barb 🔽 female 1 (ASA male In confidence Therapy dates (if unknown, give duration) 2. Dose, frequency & route used B. Adverse event or product problem 10/17 . 10172 Product problem (e.g., defects/malfunctions) Adverse event and/or 10/17. 10/22 #2 325 disability (check all that apply) 4. Diagnosis for use (indication) congenital anomaly stopped or dose reduced death _ required intervention to prevent #1 yes no goesn' Me-threatening permanent impairment/damage ACS hospitalization - initial or prolonged #2 yes no doesn't 6. Lot # (If known) 7. Exp. date (if known) 4. Luie of 8. Event reappeared rifter Svent 10/22/2000 reintroduction #2 #1 yes: no doesn't 9. NDC # (for product problems only) pt. experienced upon GI bletd/ #2 yes no soon 10. Concomitant medical products and therapy dates (exclude treatment of evert) ASAID Prior to examination, with of duodenal vices with resultant Lieutement conteners dos schronen ormostatic hypotensim. Loss 6 D. Suspect medical device consciousness 30-45 servids ,. h. 2. Type of device gray puller and the 130's 4. Operator of devi > 3. Manufacturer name & address health professional Treated with amegint and on ory lay user/patient other: olces, Benits JABC, omgratile to Expiration del If implented, give date H pylor, (+) 8. If explanted, give date (Do not send to FDA) yes returned to manufacturer on Other relevant history, including pressisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) 21. on NEAD prise to hospital altinis, an. CTU 143439

. Repor	rter (see co	nfidentiality sec	ction on back)
Name & ad		phone #	Dec
			_ しここ
	## A	tal	MHY 1 1 2001
Health profe	esional? 3. C		4. Also reported to
∑ yes [□ no ;;	A -water	rnanufactur
		entity disclosed to	



Mail to: MEDWATCH 5600 Flahers Lane Rockville, MD 20852-9787

or FAX to: 1-800-FDA-0178 THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

DLUNTARY reporting h professionals of adverse 5 and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/94 See OMB statement on reverse

FDA Use Only Triage unit

A. Patient i	nformation			C. Suspect medic	cation(s	3)	
1. Patient identifier	2. Age at time	3. Sex	4. Weight	Name (give labeled streng		•	
5250	of event:	X fer		#1 USPILLY			
In confidence	Date of birth:	☐ ma	ale kgs	#2			·
<u> </u>	event or produ	ict problem	kgs	2. Dose, frequency & route	used	3. Therapy date	es (if unknown, give duration)
1. Adverse eve		oduct problem (e.g., defe	ects/malfunctions)	" a tabs at h		#1 1 3 6	- 1134 01
2. Outcomes attrib	uted to adverse event	disability		#2		#2	
(check all that app	Ply)	congenital anomaly	,	4. Diagnosis for use (indicat			Event abated after us:
death	(morday/yr)	required intervention	n to prevent	1 Headache			stopped or dose reduced
life-threatening	_	permanent impairm	ent/damage	#2	 		#1 yes no do ssn
nospitalizatio	en - initial or prolonged			6. Lot # (if known)	7 Exp de	ate (if known)	#2 yes no do:sn
3. Date of event	ala.	4. Date of this report	101	#1	#1	 	8. Event reappeared after
(mo/day/yr) 5. Describe event	13 01	(mo/day/yr)	(101	#2	#2		reintroduction
S. Describe event	o. prodicin			9. NDC # (for product problem	ns only)		#1 yes no Agousn
					-		#2 yes no doesn
55 YO	adm on 1/23 for	hematemesis. P	with	10. Concomitant medical pr	roducts and	therapy cates (e)	clude treatment of event)
hx of al	bdominal pain, on	omeprazole. At	1am	Daproten (al	aum,	Cloudin	- Departure
and c/c	B, pt vomited black mild epigastric p	t material then bid ain. On the way t	o HD	Feresemide, N	izphwci	was iffer	tumirio, he -
the nex	ct day, pt vomited	blood then vomite	ed l b	İ	1	1	•
ithroat r	. 100ml at HD. In pain, dizziness, an	ER, pt c/o tongue	and	D. Suspect medi	cal dovi	CO	
hypoter	nsive 100s/30s. H	R= 100-110s, and	tan l	Brand name	cai acvi		
EKG sh	nowed peaked T v gluconate, insuli	vaves. Pt treated	with	C. Turn of device			
Pt vom:	ited an additional.	250ml blood. Mei	lena I I	2. Type of device			
noted.	Obstructive series	neg. NG lavage	=2L	3. Manufacturer name & add	dress [200	4. Operator of device
and ran	Pt given PRBCs a nitidine. As per sis	ster, ot taking aspi	irin 2 l		<u>L_</u>	700	health professior at
tabs	94 x 1. Sweeks	for headacha			MAY	1 8 2001	lay user/patient other:
						z o 2001	
							5. Expiration date
				6.			(mo/day/y _i)
6 Palayant tasts/is	aboratory data, including	dates		model # RF(CFIV	FD	
o. nelevant tests/a	33 1/24	uales		catalog #			7. If implanted, give date (mo/day/yr)
Hab 6.	5 la la			serial # MA	Y 1 7 7	001	
l o	1 23			lot # A A C C \ A	ATOLI	CTU	8. If explanted, give date (mo/day/y
1.0	-			I Other#	AIUI		
bit 108	احوا کا			Device available for evaluation	uation?	(Do not send	I to FDA)
SCr	К			yes no	retu	rned to manufact	urer on
K 6				10. Concomitant medical pr	roducts and	therapy dates (e:	
	istory, including preexi	sting medical condition	es (o.o. allergies				
race, pregnancy,	smoking and alcohol use	, hepatic/renal dysfunction					
ANH ESK	? P on hemor	tialysis		E. Reporter (see	confident	iality section	on back)
HT	\sim	t		1. Name, address & phone			narmD
LV	14	Allergies	NKDA	Hospital E			
New	mathic Pain	,)		Department	_	y Services	
Ank	S on hemou 1H mathic Pain 1ety	Allergies CTG			Street -	1	
Chr	onic Back Pain	019	43629	2. Health professional? 3.	Occupant		4. Also reported to
<u> </u>	· · · · · · · · · · · · · · · · · · ·	· - · · · · · · · · · · · · · · · · · ·		yes no	Pharmaci		manufacturer
	Mail to: MEDWATCH 5600 Fishers	Lane 1-80	to: 0-FDA-0178	5. If you do NOT want you			user facility
		D 20852-9787		the manufacturer, place			distributor





"+" indicates item continued

Approved by	FDA OB	12/02/91	
Mfr report #	A0316	96	i
UF/Dist report	#		
ļ		EDA	Lica Only

Page 1 of 8

A. Patient li	nformation				C. Suspect me	edication	(s)		
1.Patient Identifier			3. Sex	4. Weight	1. Name (give labeled str	rength & mfr/labe	eler, if known)		
	of event:	UNKNOWN		UNK Ibs	# 1 NORVASC TABLETS				
	or — Birth:		Fernale	or	# 2 MEVACOR				Cont.
in confidence	Date of Birth:		☐ Male	kgs	2. Dose, frequency &	route used	3.Therapy	ates (if u	nknown, give duration)
B. Adverse				M	# 1 5:00 MG TOTAL:DAILY:0		# 1 09/10	from. 0/93 - 09 .	/to (or best estimates)
1. 🔀 Adverse ever			(e.g. defects/n	natifunctions)	# 2 20.00 MG TOTAL:DAILY	:ORAL	#2 -/-/	91 - UNK	CNOWN
2. Outcomes attrib		event M disabilit	y		4. Diagnosis for use	(indications) +		5. Even	t abated after use d or dose reduced
death		-	ital anomaly		# 1 HYPERTENSION			Stoppe	dcesn't
life-threatening	day/yr)	require	d intervention to ent impairment	o prevent t/damage	# 2 HIGH CHOLESTEROL			# 1 🛛 ye	es no apply dcesn t
	- initial or prolonged	other:			6. Lot # (if known)	7. Exp. da	te (if known)	#257	apply
3. Date of		4. Date of	ort 05/11/	/n1	#1 UNKNOWN	#1 UNKN	OWN		es 🔀 no 🗆
event 07 (mo/day/yr)	/25/94	this repo			#2 UNKNOWN	#2 UNKN	OWN	reint	roduction
5. Describe event					9. NDC # - for product	problems only	(if known)	[†] #1□\	dcesn't yes 🗍 no 🔀 apply
ADDITIONAL IN	FORMATION REP	ORTED TO PF	IZER ON 0	LMAY01	i	p,		<u> </u>	dcesn't
CHANGES THE C	BE UNEXPECTE	D ACCORDING	TO THE U	SPI.	i				res 🔀 no 🔲 apply
mure 60-VEAR-	OLD (CURRENT	AGE) FEMALE	CONSUMER	REPORTS	10.Concomitant med		and therapy d	ates (exclu	ude treatment of event)
THAT SHE STAR IN 98 FOR HYP	TED TAKING NO	RVASC (AMIA ER BLOOD PR	ESSURE PR	IOR TO	HYDROCHLOROTHIAZ EVISTA	IDE		07/16	OWN - 09/11/00 5/98//98
MORVASC TREAT	MENT WAS 160/	85MMHG. "5	HORTLY AF	TER	PREDNISONE				5/98//98 -/99//99
STARTING" NOR	VASC, IN 98,	SHE EXPERIE	NCED SWEL	LING TO	CORTISONE DIOVAN			09/11	L/00 - PRESENT
HER ANKLES AN		SHE WAS TI 99, SHE W	REATED WIT	ON EVIST	22201			06/13	3/00 - PRESENT +
HOSE AND BABY	TYDROCHLORIDE)	FOR UNKNOW	IN REASONS	. IN 99,	G. All manufa	cturers			
THE SWELLING	WAS TREATED W	ITH FUROSE	MIDE AND "	HCTZ" WAS			e mfring site for	devices)	2. Phone number
ADDED TO LOWE	R HER BLOOD P	RESSURE, E	VEN THOUGH	SHE	PFIZER REGULATORY SAFETY PFIZER PHARMACEUTICALS 235 EAST 42 STREET 3. Report sou				212-573-3129
REPORTS THAT	THE NORVASC W	ISTIRE 130/8	ON CONTRO	RVASC					
THERAPY). IN	99. SHE HAD	AN ULTRASO	UND OF HER	LEGS,					3. Report source
WHICH WAS NOT	RMAL. IN 2000	, SHE DID	NOT TAKE N	ORVASC FO					(check all that apply)
3 OR 4 DAYS	BECAUSE SHE LI	FT IT HOME	WHEN SHE	TRAVELED					foreign
PERITMS & LT	RIENCED FEELIN	TED. IN TH	E 3 OR 4 D	AYS SHE					study
DID NOT TAKE	NORVASC THERE	g "May" hav	E BEEN SOM	E SLIGHT					☐ I terature
DECREASE IN	IN THE SWELLI	NG.	/CEDTUS CT1	ATEN FOR					-
IN AUG00, SH	E WAS STARTED	EPOO, THE P	HYSICI AN	1110, 101	4. Date received by	manufacture	5.		consumer
HIGH CHOLEST	EROL. OH 115				(mo/day/yr)	11101101010101	1(A)		health professional
					09/11/00		NDA # NDA	19-787	user facility
6 Polevant tests	/laboratory data	including dates			6. If IND, protocol #		PLA#		company representative
1	OR TO NORVASC: E				•		pre-1938		distributor (1)
UNKNOWN DATE PAI	AFTER NORVASC: E	LOOD PRESSURE	130/80MMG		N/A		0.70		□ other
	LEGE WAS NORMAL.				7. Type of report		product L	yes	
					(check all that apply))	8. Adverse	event t	erm(s)
FOLLOW-UP (225E)	REVEALED NO VASCI	JLAR PROBLEM.			☐ 5-day 🔀 15-d	iay	DIZZINESS		Dee
1.10 0221					10-Day peri	odic	HEADACHE VERTIGO		1200
FOLLOW-UP (23JA)	(01) :				+ 🔀 initial 🔲 follo	w-up #	CONJUNCTIV TINNITUS	ITIS	DSS - *** 1 8 200
	A blake in the standing	a propulable	medical co	nditions	┥ ̄ ̄		ABDOMINAL	PAIM	: # // 00
7. Other relevan	nt history,includia e, pregnancy, smokin	ng preezising	henstic/rensl c	ivsfunction.etc	9. Mfr. report numb	er	ECCHYMOSIS		THEROPITON
1		iy a diconol use,	rispanorional C	.,	A031696	\$	RESPIRATOR BRONCHITIS		INFECTION
- PRIOR TO NORVE								سفيد	+
OBESE					E. Initial rep	orter			
NONSMOKER					1. Name , address	& phone #		4	
VARICOE VEINS-R	IGHT LEG:								
PIGET CALF MUSC	LE INJURY/PAIN:				ROAD	*			
1	LE FILING PAPER I	N BOTTON DRAW	ER OF LATERAL	, FILE; MUSC	+ Tel				+
SPASM 25JUN93				an admissis-	<u> </u>	? 3. Occupa	ation	4. Initi	al reporter also
	Submission of that medical pe	a report does r ersonnel, user f	acility, distrib	utor, manufa	yes 🔀 no				t report to FDA es ☐no 🔀 unii



cumission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

3. Occupation	4. Initial reporter also sent report to FDA
UNEMPLOYED	yes no 🔀 unk

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	Approved by FDA or: 12/02.93 Mfr report # A031696
	UF/Dist report #
Page 2 of 8	FDA Use Only

C. Suspect me	edication	(s)		
1. Name (give labeled s	rength & mfr/lab	eler, if known)		
#3 EXCEDRIN				
#4 LEVAQUIN				
2. Dose, frequency & # 3 NOT SPECIFIED	route used	1	dates(if unknown, give duration) from/to (or best estimates) (NOWN	
# 4 500.00 MG TOTAL:DAIL	4 500.00 MG TOTAL DAILY ORAL # 4 04/-/98 - UNKNOWN			
4. Diagnosis for use #3 INDICATION UNKNOWN	(indications)		5. Event abated after use stoped or dose reduced UNKNOWN doesn't	
# 4 URINARY URGENCY BACK PAIN			#3 yes no apply UNKNOWN	
6. Lot # (if known) #3 unknown	7. Exp. da #3 UNKN	ite (if known	# 4 yes no apply 8. Event reappeared after reintroduction	
#4 UNKNOWN #4 UNKN		IOWN	reintroduction UNKNOWN dicesn' # 3 yes no apply	
			#4 yes X no apply	

DSS MAY 1 8 2000

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B5. EVENT DESCRIPTION - Continued

DISCONTINUED THE MORVASC DUE TO THE EVENTS.

FOLLOW-UP (22SEP00): THE CONSUMER REPORTS SHE DEVELOPED EDEMA WHICH CAUSED A LOT OF PAIN, PRESSURE AND LIMITED HER MOBILITY. HER FAMILY PHYSICIAN SUGGESTED THAT SHE MAY HAVE A VASCULAR PROBLEM. HER PHYSICIAN RECOMMENDED SHE SEE A VASCULAR SURGEON. THE PATIENT REPORTS THAT THE VASCULAR SURGEON PERFORMED AN EXAMINATION INCLUDING 2 ULTRASOUNDS. THE VASCULAR SURGEON DID NOT THINK THERE WAS A VASCULAR PROBLEM. THE PATIENT WENT TO SEE A SECOND VASCULAR SURGEON WITH THE SAME RESULTS. THE PATIENT REPORTS THAT HER FAMILY PHYSICIAN NOW CONSIDERS IT VERY POSSIBLE THAT NORVASC HAD BEEN CAUSING THE EDEMA ALL ALONG. THE PHYSICIAN SUGGESTED THAT PATIENT STOP THE NORVASC IMMEDIATELY, WHICH SHE DID.

FOLLOW-UP (23JAN01): A PHYSICIAN SUPPLIED THE PATIENT'S MEDICAL RECORD. AS OF 08OCT98, THE MEDICAL RECORD INDICATED THAT THE OBESE PATIENT USED TO WALK ABOUT 5 MILES A DAY UNTIL RECENTLY BUT NOW SHE HAD A MOVING PAIN IN HER LEFT LEG. SHE WAS ON PREDNISONE FOR 2 WEEKS IN THE PAST AND THE PAIN MAY HAVE GOTTEN BETTER. SHE HAD NO HISTORY OF DEEP VEIN THROMBOSIS (DVT). ON PHYSICAL EXAM, THERE WAS NO EVIDENCE OF THROMBOLIC SKIN CHARACTERISTICS. THE PATIENT WAS DIAGNOSED WITH SUPPORTIVE VARICOSE VEINS. THE PATIENT WAS TAKING ASPIRIN DAILY. A DOPPLER STUDY WAS PLANNED AND THE PATIENT WAS INSTRUCTED TO WEAR SUPPORT STOCKINGS AND TO AMBULATE. ON 12OCT98, A VENOUS DOPPLER STUDY WAS ABNORMAL WITH NO EVIDENCE OF DVTS. THE PATIENT WAS ADVISED TO WEAR SUPPORT COMPRESSION STOCKINGS. THE DIAGNOSIS WAS VARICOSE VEINS WITH VENOUS INSUFFICIENCY.

FOLLOW-UP (13FEB01): A PHYSICIAN PROVIDED THE RESULTS OF TWO LOWER EXTREMITY VENOUS DUPLEX SCANS. THE FIRST SCAN, PERFORMED ON 15SEP99, WAS INDICATED FOR RIGHT LOWER EXTREMITY PAIN AND EDEMA. THE SECOND SCAN, PERFORMED ON 01DEC99, WAS INDICATED FOR RIGHT LOWER EXTREMITY EDEMA. BOTH SCANS SHOWED INCOMPETENCE OF THE COMMON FEMORAL VEIN WITH NO EVIDENCE OF DEEP VEIN THROMBOSIS IN THE RIGHT LOWER EXTREMITY.

FOLLOW-UP (29MARO1): THIS PHYSICIAN REPORTS THAT THIS HE DID NOT PRESCRIBE NORVASC (AMLODIPINE). HE TREATED HER FOR VENOUS INSUFFICENCY, WHICH MAY HAVE CONTRIBUTED TO HER SWELLING. HE PERFORMED A LOWER EXTREMITY VENOUS DUPLEX SCAN, WHICH REVEALED SWELLING IN THE RIGHT LEG AND REFLUX IN HER RIGHT COMMON FEMORAL VEIN, EVERYTHING ELSE ON THE SCAN WAS NORMAL. THE PHYSICIAN'S CONCLUSION OF THE DUPLEX IMAGING WITH COMPRESSION SHOWS NO THROMBUS IN THE COMMON FEMORAL, SUPERFICIAL FEMORAL, POPLITEAL, POSTERIOR TIBIAL, PERONEAL AND GREATER SAPHENOUS VEINS. THERE IS NO EVIDENCE OF DEEP VEIN THROMBOSIS. INCOMPETENT "CFV".

FOLLOW-UP (01MAY01): A PHYSICIAN SUPPLIED THE PATIENT'S MEDICAL RECORD. AS OF 10SEP93, THE MEDICAL RECORD INDICATED THE PATIENT WAS ON NORVASC 5MG DAILY. THE PATIENT WAS ALSO CONTINUING TO TAKE HYDRODIURIL (HYDROCHLOROTHIAZIDE) 50MG. ON 14JAN94, WHEN THE PATIENT'S CHOLESTEROL WAS 247 AND HER BLOOD PRESSURE WAS 160/100, NORVASC WAS TEMPORARILY DISCONTINUED. ON 20MAY94, NORVASC 5MG WAS RENEWED FOR THREE DOSES. ON 25JUL94, THE PATIENT'S BLOOD PRESSURE WAS 145/95 AND HER CHOLESTEROL WAS 255. THE DOSE OF MEVACOR (LOVASTATIN) 20MG WAS INCREASED TO TWO TABLETS DAILY FOR SEVEN DAYS. ON 23MAR95, THE PATIENT STATED THAT TWO WEEKS AGO SHE FELT LEFT RIB PAIN AFTER TWISTING MOTION. THE PATIENT CONTINUED TO TAKE NORVASC IN 1996 AND CAME IN FOR A FOLLOW-UP VISIT TO CHECK HER HYPERTENSION AND CHOLESTEROL ON 31JAN97. HER BLOOD PRESSURE WAS 140/80 AND SHE WEIGHED 200 POUNDS. THE PATIENT WAS INSTRUCTED TO CONTINUE NORVASC 5MG DAILY AND HYDRODIURIL FOR HYPERTENSION AND MEVACOR 20MG DAILY FOR HIGH CHOLESTEROL. SHE WAS STARTED ON HORMONE REPLACEMENT THERAPY (ESTRADIOL 1MG AND PROGESTERONE) AND WAS SENT FOR A MAMMOGRAM. SHE HAD AN UPPER RESPIRATORY INFECTION, WHICH WAS RESOLVING. ON 17FEB97, THE PATIENT COMPLAINED OF A SEVERE SORE THROAT AND WAS PRESCRIBED AMOXICILLIN 500MG. HER TEMPERATURE WAS 98.4. ON 16JUN97, THE PATIENT HAD A TEMPERATURE OF 99.5 AND COMPLAINED OF SORE THROAT, SWOLLEN GLANDS, AND "PUFFY" EYES. SHE WAS DIAGNOSED WITH ALLERGIC RHINITIS AND CONJUNCTIVITIS (HISTAMINE ALLERGIC). SHE WAS PRESCRIBED LIVOSTIN (LEVOCABASTINE) EYE DROPS FOR HER LEFT EYE AND RECEIVED 0.5CC DEPO MEDROL (METHYLPREDNISOLONE) AND ZYRTEC (CETIRIZINE).

ON 21JUL97, THE PATIENT COMPLAINED OF EXCESSIVE THIRST RECENTLY. THE DRY MOUTH WAS CONSIDERED TO BE PCSSIBLY RELATED TO EXCEDRIN (ACETAMINOPHEN, CAFFEINE, ASPIRIN) USE. A URINALYSIS WAS POSITIVE FOR BLOOD (UA: 4+ BLOOD).

BUT WAS NEGATIVE FOR GLUCOSE. THE PATIENT RECEIVED A FLU VACCINE ON 20NOV97. ON 10APR98, THE PATIENT EXPERIENCED URINARY URGENCY AND TOOK MACROBID (NITROFURANTOIN). HER CULTURES INDICATED SHE HAD E. COLI, BUT HER URINALYSIS WAS NEGATIVE. SHE EXPERIENCED BACK PAIN, FEVER, CHILLS AND ABDOMINAL PAIN. THE PHYSICIAN DISCONTINUED THE MACROBID AND PRESCRIBED LEVAQUIN (LEVOFLOXACIN) 500MG DAILY FOR FIVE DAYS. ON 14APR98, THE PATIENT COMPLAINED OF DIARRHEA AND WAS ADVISED TO STOP THE LEVAQUIN. ON 16JUL98, THE PATIENT WAS GIVEN EVISTA. SHE DEVELOPED PAINS IN HER LEGS AND STOPPED TAKING THE MEDICATION. THE PATIENT'S BREAST BIOPSY WAS NEGATIVE. THE PATIENT WAS GIVEN RELAFEN (NABUMETONE) DAILY FOR THE PAIN IN HER VARICOSE VEINS. ON 25AUG98, THE PATIENT LOST SIX POUNDS AND WEIGHED 206 POUNDS. HER TEMPERATURE WAS 98.8. SHE COMPLAINED OF UPPER RESPIRATORY. INFECTION SYMPTOMS WITH COUGH FOR FOUR DAYS. SHE WAS DIAGNOSED WITH BRONCHITIS AND WAS PRESCRIBED AMOXIL (AMOXICILLIN) AND PREDNISONE.

ON 27AUG98, THE PATIENT RETURNED TO THE PHYSICIAN'S OFFICE WITH BLOODY SPUTUM AND DIZZINESS. THE PATIENT NOTED EXPERIENCING AN ADVERSE DRUG REACTION TO PREDNISONE (COUGH PRODUCTION OF YELLOW SPUTUM). THE PATIENT WAS PRESCRIBED HYCODAN (HYDROCODONE/HOMATROPINE) SYRUP. ON 03SEP98, THE PATIENT INDICATED SHE VOMITED ONE DAY AGO AND EXPERIENCED NAUSEA, CONCESTION AND FRONTAL HEADACHE. SHE HAD DIARRHEA AND HEMORRHOIDS WITH A SMALL AMOUNT OF RECTAL BLEEDING, WHICH RESOLVED SPONTANEOUSLY. THE PHYSICIAN RECOMMENDED HAVING A COLONOSCOPY, WHICH THE PATIENT REFUSED. THE MEDICAL RECORD ON 29SEP98 INDICATED THE PATIENT WENT TO AN ORTHOPEDIST FOR HER LEG PAIN. SHE HAS NO ARTHRITIS IN HER JOINTS. SHE WAS PRESCRIBED VOLTAREN (DICLOFENAC) SOMG TWICE DAILY AFTER MEALS AND HER RELAFEN WAS DISCONTINUED. +

DSS



B6. RELEVANT TESTS/LAB. DATA - Continued

120CT98: VEMOUS DOPPLER STUDY WAS ABNORMAL WITH NO EVIDENCE OF DVTS, DIAGNOSIS OF VARICOSE VEINS WITH VENOUS INSUFFICIENCY; RIGHT LEG VENOUS TEMPERATURE 25.9, LEFT LEG VENOUS TEMPERATURE 28.8.

FOLLOW-UP (13FEB01): 15SEP99: LOWER EXTREMITY VENOUS DUPLEX SCAN - INCOMPETENT COMMON FEMORAL VEIN WITH NO EVIDENCE OF DEEP VEIN THROMBOSIS; NO THROMBUS IN THE COMMON FEMORAL, SUPERFICIAL FEMORAL, POSTERIOR TIBIAL, PERONEAL AND GREATER SAPHENOUS VEINS.

01DEC99: LOWER EXTREMITY VENOUS DUPLEX SCAN - NO CHANGE

FOLLOW-UP (29MAR01):

UNSPECIFIED DATE:

LOWER EXTREMITY VENOUS DUPLEX SCAN, WHICH REVEALED SWELLING IN THE RIGHT LEG AND REFLUX IN HER RIGHT COMMON FERMORAL VEIN, EVERYTHING ELSE ON THE SCAN WAS NORMAL. THE PHYSICIAN'S CONCLUSION OF THE DUPLEX IMAGING WITH COMPRESSION SHOWS NO THROMBUS IN THE COMMON FEMORAL, SUPERFICIAL FEMORAL, POPLITEAL, POSTERIOR TIBIAL, PERONEAL AND GREATER SAPHENOUS VEINS. THERE IS NO EVIDENCE OF DEEP VEIN THROMBOSIS. INCOMPETENT "CFV".

FOLLOW-UP (01MAY01):

14JAN94: CHOLESTEROL: 247MG/DL, BLOOD PRESSURE: 160/100

25JUL94: CHOLESTEROL: 255MG/DL, BLOOD PRESSURE: 145/95.

31JAN97: BLOOD PRESSURE: 140/80, WEIGHT: 200 POUNDS, GLUCOSE (NON-FASTING): 81 MG/DL (65-130), URIC ACID: 3.7MG/DL (2.6-8.1), PHOSPHATE 2.9MG/DL (2.5-4.5), CALCIUM: 9.4MG/DL (8.7-10.2), MAGNESIUM: 1.73 MEQ/DL (1.4-2.0), ALK PHOSPHATASE: 76 UNITS/L (30-162), G- GLUTAMYL TRANSPEP. 20 UNITS/L (1-78), AST (SGOT): 1) IU/L (1-45), ALT (SGPT): 25 IU/L (1-50), LD: 180 IU/L (90-250), IRON: 72MCG/DL (45-145), BUN: 16MG/DL (8-24), CREATININE: 0.8MG/DL (0.6-1.2), BUN/CREATININE RATIO: 20, TOTAL PROTEIN: 7.2 GM/DL (6.3-7.9), ALBUMIN: 4.2GM/DL (3.6-4.7), GLOBULIN: 3.0GM/DL (2.2-3.7), ALB/GLOB RATIO: 1.4 (1.0-2.0), TOTAL BILIRUBIN: 0.32MG/DL (0.2-1.1), DIRECT BILIRUBIN: 0.05MG/DL (0.0-0.2), SODIUM: 138 MMOL/L (135-144), POTASSIUM: 3.9 MMOL/L (3.4-5.2), CHLORIDE: 99 MMOL/L (94-107), WBC: 7.3 THOUS./CU.MM (3.9-11.2), RBC: 4.4 MIL/CU.MM (3.8-5.2), HGB: 12.6 GM/DL (11.6-15.5), HCT: 36.3 PERCENT (34-46), MCV: 83FL (80-98), MCH: 28.7PG (27-34), MCHC: 34.7 PERCENT (32-36), RDW: 13.5 PERCENT (11-15.5), PLATELET COUNT: 229 THOUS./CU .MM (150-400), POLY (62.3 PCT): 4547 CU.MM (1700-8500), LYMPH (28.3 PCT): 2065 CU.MM (1000-3500), MONO (7.6 PCT): 554 CU.MM (40-900), EOS (1.3 PCT): 94 CU.MM (30-550), BASO (0.5 PCT): 36 CU.MM (0.0-125), CHOLESTEROL: 246MG/DL (160-266), CHOL PERCENTILE: 59 PERCENTILE (1-75), HDL CHOLESTEROL: 37MG/DL (49-96), CHOL/HDL RATIO: 6.6 (ASSOCIATED WITH THE HIGHEST CORONARY HEART DISEASE (CHD) RISK), TRIGLYCERIDES: 372MG/DL (50-200)

17FEB97: TEMP: 98.4

16JUN97: TEMP: 99.5

21JUL97: URINALYSIS: 4+ BLOOD, GLUCOSE NEGATIVE

10APR98: CULTURES: E. COLI, URINALYSIS: NEGATIVE

16JUL98: TSH SERUM: 2.3 MU/L (0.4-4.2), WEIGHT: 212 POUNDS, BREAST BIOPSY: NEGATIVE

25AUG98: WEIGHT: 206 POUNDS, TEMP: 98.8, LUNGS: WHEEZES/RHONCHI

060CT98: WEIGHT: 208 POUNDS

02NOV98: MAMMOGRAPHY AND ULTRASOUND OF RIGHT BREAST: MASS LESION NOT IDENTIFIED

08DEC98: GLUCOSE (NON-FASTING): 77MG/DL (65-125), URIC ACID: 3.7MG/DL (1.7-6.1), PHOSPHATE: 3.8MG/DL (2.5-4.7) CALCIUM: 10MG/DL (8.5-10.3), MAGNESIUM: 2.07MG/DL (1.5-2.5), ALK PHOSPHATASE: 71.0 UNITS/L (30-105), GGT: 26 UNITS/L (5-55), AST (SGOT): 22 IU/L (5-35), ALT (SGPT): 29 IU/L (5-40), TOTAL LD: 189 IU/L (100-215), IRON: 66MCG/DL (35-175), BUN: 17MG/DL (7-20), CREATININE: 0.8MG/DL (0.5-1.0), BUN/CREATININE RATIO: 21.3, TOTAL PROTEIN: 7.1GM/DL (6.4-8.2), ALBUMIN: 4.2GM/DL (3.7-4.9), CALC. GLOBULIN: 2.9GM/DL (2.2-3.7), A/G RATIO: 1.45 (1.0-1.9), TOTAL BILIRUBIN: 0.34MG/DL (0.2-1.2), DIRECT BILIRUBIN: 0.13MG/DL (0.0-0.2), SODIUM: 143MMOL/L (135-144), POTASSIUM: 3.6MMOL/L (3.5-5), CHLORIDE: 102MMOL/L (99-109), CHOLESTEROL: 234MG/DL (120-215), HDL CHOLESTEROL: 36MG/DL (47-89), CHOL/HDL RATIO: 6.5, CALCULATED LDL CHOL: 132MG/DL (57.3-146), TRIGLYCERIDES: 331MG/DL (40-199)

26JAN99: WEIGHT: 204 POUNDS

19FEB99: WEIGHT: 211 POUNDS

16MAR99: KNEE X-RAY: WITHIN NORMAL LIMITS



01JUN99: WEIGHT: 208 POUNDS

22JUL99: WEIGHT: 210 POUNDS, BLOOD PRESSURE: 130/80, AST (SGOT): 22 IU/L (5-35), ALT (SGPT): 38IU/L (5-40), ALK PHOSPHATASE: 72 UNITS/L (30-130), GLUCOSE (NON-FASTING): 84MG/DL (65-125), CALCIUM: 9.6MG/DL (8.5-10.3), BUN: 16MG/DL (8-25), CREATININE: 0.8MG/DL (0.5-1.1), BUN/CREATININE RATIO: 20, TOTAL PROTEIN 7.1GM/DL (6.3-8.2), ALBUMIN: 4.2GM/DL (3.7-4.7), CALC. GLOBULIN: 2.9GM/DL (2.2-3.8), A/G RATIO: 1.45 (1-2), TOTAL BILIRUBIN: 0.44MG/DL (0.2-1.1), DIRECT BILIRUBIN: 0.06MG/DL (0.0-0.2), SODIUM: 141MMOL/L (136-145), POTASSIUM: 3.5MMOL/L (3.5-5.2), CHLORIDE: 103MMOL/L (99-109), CARBON DIOXIDE: 26MMOL/L (21.3-30.5), T3 UPTARE: 35.4 PERCENT (27.8-40.7), SERUM TSH: 2.8 MU/L (0.4-4.2), T4 AS THYROXINE: 9MCG/DL (4.5-12.0), CALCULATED FREE T4: 3.22 UNITS (1.75-3.8), WBC: 6.2 THOUS./CC.MM (3.9-11.2), RBC: 4.2MIL./CU.MM (3.8-5.2), HGB: 12GM/DL (11.6-15.5), HCT: 35 PERCENT (34-46), MCV: 83 FL (80-98), MCH: 28.5PG (27-34), MCHC: 34.2 PERCENT (32-36), RDW: 14.4 PERCENT (11-15.5), MPV: 10FL (7.5-11.5), AUTO PLATELET C OUNT: 186 THOUS./CU.MM (150-400), POLY (55.7 PCT) 3453 CU.MM (1700-8500), LYMPH (31.3 PCT): 1940 CU.MM (1000-3500), MONO (10.9 PCT): 675 CU.MM (40-900), EOS (1.1 PCT): 68 CU.MM (30-650), BASO (1.0 PCT): 62 CU.MM (0.0-125), SERUM CHOLESTEROL: 225MG/DL (120-199), HDL CHOLESTEROL: 28MG/DL (35-59), CHOL./HDL RATIO: 8.03 (3-5.5), CALCULATED LDL CHOLESTEROL: 119MG/DL (75-129, TRIGLYCERIDES: 392MG/DL (40-199) 18NOV99: WEIGHT: 206 03JAN00: WEIGHT: 212 POUNDS JAN00 OR FEB00: MRI: POSITIVE FOR TORN MEDIAL MENISCUS (TMM) 29FEB00: WEIGHT: 204 LBS, GLUCOSE (NON-FASTING): 94MG/DL (65-125), SODIUM: 142MMOL/L (136-145), POTASSIUM: 3.2 MMOL/L(3.5-5.2), CHLORIDE: 99MMOL/L (98-109), CARBON DIOXIDE: 30MMOL/L (21-31), UREA NITROGEN: 19MG/DL (9-26), CREATININE: 0.8MG/DL (0.5-1.1), BUN/CREATININE RATIO: 23.8, URIC ACID: 3.7MG/DL (1.7-7.2), PHOSPHATE: 3.8MG/DL (2.5-4.5) CALCIUM: 10MG/DL (8.5-10.3), TOTAL CHOLESTEROL: 288MG/DL (120-199), TRIGLYCERIDES: 483MG/DL (40-199), TOTAL PROTEIN: 7.8G/DL (6.3-8.2), ALBUMIN: 4.4G/DL (3.7-4.7), CALCULATED GLOBULIN: 3.4G/DL (2.2-3.8), A/G RATIO 1.3 (1.0-1.8), TOTAL BILIRUBIN: 0.37MG/DL (0.2-1.1), DIRECT BILIRUBIN: 0.05MG/DL (0.0-0.2), ALKALINE PHOSPHATASE: 71U/L (30-130), GGT: 31U/L (5-60), AST: 22U/L (5-35), ALT: 33U/L (5-40), LD: 186U/L (100-230), IRON: 69UG/DL (40-150), WBC: 5.6 THOUS./CU.MM (3.9-10.9), RBC: 4.43 MIL./CU.MM (3.8-5.2), HEMOGLOBIN: 12.8G/DL (11.6-15.6), HEMATOCRIT: 37.2 PERCENT (34-47), MCV: 84FL (80-98), MCH: 28.9PG (27.2-34.0), MCHC: 34.4 FERCENT (32-36), RDW: 14 PERCENT (11.0-15.5), PLATELET COUNT: 235 THOUS./CU.MM (150-400), MPV: 9.5FL (7.5-11.5), TOTAL NEUTROPHILS: 53.7 PERCENT (38-80), TOTAL LYMPHOCYTES: 35.3 PERCENT (15-49), MONOCYTES: 8.9 PERCENT (0-13), EOSINOPHILS: 1.4 PERCENT (0-8), BASOPHILS: 0.7 PERCENT (0-2), ABSOLUTE NEUTROPHILS: 3007 CELLS/CU.MM (1700-8500), ABSOLUTE LYMPHOCYTES: 1977 CELLS/CU.MM (1000-3500), ABSOLUTE MONOCYTES: 498 CELLS/CU.MM (40-900), ABSOLUTE EOSINOPHILS: 78 CELLS/CU.MM

13JUN00: WEIGHT: 208 POUNDS, CHOLESTEROL: 274MG/DL, K: 3.02MMOL/L

MS, QRS DUR: 96 MS, QT/QTC: 388/427 MS, P-QRS-T AXES: 47-13-24

11SEP00: T: 97.4, BLOOD PRESSURE: 180/105, URINALYSIS: TRACE BLOOD AND LEUKOCYTES AND WAS NEGATIVE FOR GLUCOSE

(30-550), ABSOLUTE BASOPHILS: 39 CELLS/CU.MM (0-125), SINUS RHYTHM NORMAL ECG, VENT RATE: 82 BPM, PR INT: 186

06OCT00: WEIGHT: 210 POUNDS, BLOOD PRESSURE: 150/90

20FEB00: WEIGHT: 213 POUNDS, CHOLESTEROL: 240MG/DL

B7. OTHER RELEVANT HISTORY - Continued

HYPOTHYROIDISM

C4. DIAGNOSIS FOR USE (INDICATIONS) - Continued

#4 Fever

CHILLS

ABDOMINAL PAIN

C10. CONCOMITANT MEDICAL PRODUCTS - Continued

VITAMINS

UNKNOWN

E1. NAME AND ADDRESS OF REPORTER - Continued

ASSOCIATES

STREET

Tel. - UNKNOWN

DSS MAY 8200

SURGICAL GROUP AVE, STE Tel. - 6

UNKNOWN ADDRESS UNKNOWN

Tel. - UNKNOWN

MD AVENUE

G8. ADVERSE EVENT TERMS - Continued

HEMATURIA BACK PAIN

FEVER CHILLS

DIARRHEA

RECTAL DISORDER ACCIDENTAL FALL

COUGH INCREASED

ANOREXIA ABNORMAL GAIT

CONFUSION

EAR PAIN

RHINITIS

PAIN

PHARYNGITIS

URINARY URGENCY

DRY MOUTH

WEIGHT GAIN

LYMPHADENOPATHY

VOMITING

PERIPHERAL EDEMA

RECTAL HEMORRHAGE

WEIGHT LOSS

PEPTIC ULCER

VOICE ALTERATION

THIRST

HYPERLIPEMIA

RHINITIS

BONE PAIN

SKIN DISCOLORATION

POLYURIA

PERIPHERAL VASCULAR DISORDER

SPUTUM INCREASED HYPOKALEMIA

HEMOPTYSIS

HYPERTENSION

PYURIA

RASH

BREAST NEOPLASM

HYPESTHESIA

JOINT DISORDER

URINARY TRACT INFECTION

RASH

ACCIDENTAL INJURY

EVENT UNEVALUABLE

HYPOTHYROIDISM

HYPERCHOLESTEREMIA



-

Pfizer Regulatory Safety, Pfizer Pharmaceuticals - Mfr. Report # A031696

B5. EVENT DESCRIPTION - Continued

On 06Oct98, the patient complained of left leg discomfort without injury and notes discoloration at times. The physician noted the patient had venous insufficiency of the left leg, ecchymosis and pain She was advised to wear compression pants/stockings. On 02Nov98, a mammography and ultrasound of the right breast showed a mass lesion, which was not identified. The tests were ordered to be repeated in one year. On 08Dec98, the patient complained of left ear discomfort with ringing. A venous flow study was performed at a different physician's office (results unknown). The patient experienced temporomandibular pain (TMJ) pain tenderness over the left joint. Since the patient's potassium level was 3.6, K-Dur (potassium) 10meq daily was added to her antihypertensive medications consisting of Norvasc 5mg daily and Hydrochlorothiazide 50mg daily. The patient was also given Zyrtec 10mg daily for her allergic rhinitis. On 26Jan99, the patient complained of intense T-spine and dorsal discomfort. The patient also complained of stomach discomfort for one week with nausea when eating. The patient was prescribed Prilosec (omeprazole) 20mg. On 18Feb99, the patient fell while walking her dog and injured her left leg and knee. She pulled over and used ice immediately. The medical records indicate she had varicose veins in both her legs. On 19Feb99, she was given Toradol (ketorolac) intramuscularly and Voltaren XL 100mg daily. Her K-Dur dose was increased to 20meq daily. On 25Feb99, an ultrasound was performed. On 06Mar99, the patient had a productive cough and was given a prescription for Levaquin 500mg daily. The patient finished the one-week regimen, but returned to the physician's office on 15Mar99 with persistent cough. The patient complained of continued left knee pain condition, difficulty walking, limping with numbness to the left thigh. The medical records indicate the patient has been unable to work from 02Feb99 to 04Apr99. A letter from the orthopedist dated 16Mar99 indicated that a knee x-ray was within normal limits. On 19Mar99, the physician extended her disability to 19Apr99 since she still had pain and limitation of knee motion. On 01Jun99, the patient complained of left lower extremity discomfort and stated that the cortisone injection in the left knee exacerbated the discomfort. On 21Jul99, the patient met with a vascular surgeon and was diagnosed with venous insufficiency. The vascular surgeon thought her myalgias were related to her thyroid disease (patient felt tired, gaining weight, dry skin). On 18Sep99, the patient had a leg screening for peripheral vascular disease (PVD). On 18Nov99, the patient returned to the physician's office complaining of left lower extremity discomfort and was unable to ambulate comfortably. After walking one mile, the pain is exacerbated. The patient noted reddened areas on both of her ankles. The patient was prescribed Lasix (furosemide) 40mg daily. On 01Dec99, a duplex doppler indicated negative results for deep vein thrombosis (DVT). On 03Jan00, the patient complained of dry cough and congestion and was prescribed Keflex (cephalexin) 250mg three times daily. As of 29Feb00, the patient was scheduled for orthopedic surgery with general anesthesia for her right knee since a MRI result was positive for torn medial meniscus (TMM). On 21Mar00, the patient was prescribed Prilosec 20mg daily for abdominal discomfort. On 13Jun00, the patient visited the physician for a routine visit and complained of lightheadedness. The patient's cholesterol was 274mg/dl, so Mevacor was discontinued and was replaced by Baycol (cerivastatin) 0.4. On 11Sep00, the patient noted the recent death of her father and loss of her voice with hoarseness for several days. She stated she experienced excessive thirst and excessive urination. She had concerns regarding hypertension and bilateral ankle edema and had been compliant with her diuretic prescription. A urinalysis indicated trace blood and leukocytes and was negative for glucose. The patient also had transient vertigo. Due to the persistent leg edema, the patient wished to try new medication. Norvasc was discontinued and Diovan (valsartan) 80mg daily was started. Hydrodiuril was also discontinued. The patient continued to take Lasix and K-Dur for venous insufficiency and Baycol for increased cholesterol. On 14Sep00, the patient returned to the physician's office and reported experiencing adverse drug reactions of dizziness and facial outbreak with the use of Diovan. The patient notes that when using Norvasc, her blood pressure was controlled, but it caused her leg edema. The patient was started on Monopril HCT (fosinopril/hydrochlorothiazide) 10/12.5. She was given furosemide to use as needed for edema. On 06Oct00, the patient was experiencing edema in both legs since she changed medications. She was taking Lasix 40mg daily. Her Monopril HCT dose was increased to twice daily for her hypertension, but her Baycol was switched back to Mevacor 20mg daily. On 04Dec00,

DSS MAN 18 26M



B5. EVENT DESCRIPTION - Continued

the patient complained of head congestion for three days. Her cholesterol and blood pressure were maintained and the edema had resolved in both lower extremities. The patient was prescribed Levaquin and Zyrtec. On 29Dec00, the patient complained of nausea, decreased appetite especially at night, cough, head congestion and peptic ulcer disease (PUD) for a few weeks. She was prescribed Prilosec 20mg and Claritin (loratadine) 10mg. On 20Feb00, the patient visited the physician for a blood pressure and cholesterol check. Her Monopril HCT dose was increased and she was started on Lipitor (atorvastatin) for high cholesterol.

D33 MAN 1 8 70/17

COEF



PHARMACY

For VOLUNTARY reporting by health professionals of adverse events and product problems

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101VIolal Sarety Report

For VOLUNTARY reporting professionals of adverse nd product problems

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Patient identifier 2. Age at time of event: 83 9 5 5 (emails)	en Aspirin
or or	750 ma tablet (Veriter)
in confidence of birth:	2. Dose, frequency & route used 9' Therapy dates (if unknown, give duration leads (or best estimate)
a duarea event or product problem	#1 an po #1
Adverse event and/or Product problem (o.g., daracter) introduct	77
Outcomes stributed to adverse svent disability	4. Diagnosis for use (indication) 5. Event abated after use stopped or dose reduction
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	#2 Tolin #2 Jyes \(\text{No } \) does app
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event 472700 (medaylyin	#2 #2 #1 yes no 🖼 00%
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requiring PRBC transfusion 2	10. Concomitant medical products and therapy dates (exclude treatment of event)
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14129/00: mpor 2000-17	10. Concemitant medical products and therapy dates (exclude transment of event
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nace, pregnancy, amoiding and algohol use, hepatic/renal dystunction, etc.) Aug'- Sulfa, Betadine Race: Courasian	E. Reporter (see confidentiality section on back)
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Mail to: MEDWATCH or FAX to: 1-800-FDA-0178	5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box.
10-11 112 (15.4)	the manufacturer, process or the product caused or contributed to the e
FDA Form \$100 (6/63) Sufficient of a report does not constitute an admi	rission that medical personnel or the product caused or contributed to the e

Individual Safety Report

1.

Human Health Division

For use by user-facilities, listributors and manufacturers for MANDATORY reporting

Page 1

50327623 NO ATTACHMENT

Merck Facsimile of FDA Form 3500A Approved by FDA (10/21/93)

Mfr report #	WAES 01050285
UF/Dist report #	
	FDA Lise Only

A. Patient in	nformation			C. Suspec						
Patient identifier Unk	Age at time of event:	3. Sex	4. Weight	T. Name (give labeled # 1 TAB VIOXX		er, il known)				
J	or 82 years	X Female	130 pounds	#2 aspirin 325						
in confidence	Birth:	Male								
B. Adverse	event or prod	uct problem)	2. Dose, frequency & re		1	dates (from/to		-	duration)
1. X Adverse even		Product problem (e.g.,		#1 12.5 mg/D/	ILY/PU	*1_	01/01/00	- 10/* 1.	/00	_
Outcomes attributed (check all that apply)		disability		#2 325 mg/DA		# 2	01/01/00			
	ſ			4. Diagnosis for use (in	dication)		5.Event abareduced.	ated after	use stopped	a cr dose
death (m	no/day/yr)		ention to prevent	#1 Unknown #2 Unknown			yes	nc	N/A	unk
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(mo/dav/yr)	10/11/00	(mo/day/yr)	05/16/01	#2	#2		yes	по	N/A	unk
5. Describe event or prob This is in foll	nem low-up to report(s) previously	submitted on	9. NDC # - for product p	problems only (if kn	own)	#1		X	
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6. Relevant tests/laborate	ory data, including dates			(mo/day/yr)	05/10/01	AINDA-#21	.042 c		user facility	
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FDA

medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

MFR Report #:

WAES 01050285

(continue:1)

B. Adverse ever

J.

5. Describe event or problem

The patient's hemoglobin was *8.7%, hematocrit 27.1%, serum creatinine 3.6, and BUN 55. At that time rofecoxib and aspirin therapy were discontinued. A gastroscopy was performed which showed erosive, diffuse gastritis. The gastroenterology consult attributed the patient's melena, anemia, erosive, diffuse gastritis. The gastroenterology consult attributed the patient's melena, anemia, orthostasis, and gastritis to rofecoxib and aspirin. The patient was also again diagnosed with acute renal failure which was attributed by renal consult to decreased cardiac output (value not specified), volume depletion, ischemic cardiomyopathy, anemia and/or "NSAID" use. On 19-0CT-2000, the patient's serum creatinine was 1.7 and BUN 31. On 19-0CT-2000, the patient was released from the hospital. The report indicated that subsequently the patient's gastritis, melena, anemia, orthostasis, decreased cardiac output, volume depletion, ischemic cardiomyopathy, and acute renal failure subsided. failure subsided.

Follow up information has been received from the pharmacist who originally reported the information. The 82 year old female subsequently recovered from the diffuse gastritis, melena, anemia and orthostasis. Additional information is not expected.

This report was also received from the FDA through the Freedom of Information Act. There is no additional information.

This report was filed with the FDA. The CTU number is 140281 and the ISR number is 36925068.

6. Relevant tests/laboratory data, including dates

DIAGNOSTIC TEST

<u>Tests</u>	<u>Date</u>	Value Unit	No mal Range
gastroscopy	10/??/00		
Comment: erosive, diffuse gastritis			

LABORATORY RESULTS			
<u>Tests</u>	<u>Date</u>	Value Unit	Normai Range
serum blood urea nitrogen	04/??/00	44	tro ma mange
serum blood urea nitrogen	04/??/00		
Comment: almost normal			
serum creatinine	04/??/00	1.6	
serum creatinine	04/??/00		
Comment: almost normal			
hematocrit	10/11/00	27.1 %	
hemoglobin	10/11/00	"6.7" %	
serum blood urea nitrogen	10/11/00	55	
serum creatinine	10/11/00	3.6	
serum blood urea nitrogen	10/19/00	31	
serum creatinine	10/19/00	1.7	

C. Suspect medication(s)

10. Concomitant medical products and therapy dates (exclude treatment of event)

potassium chloride vitamins (unspecified) Unk - Unk Unk - Unk Unk - Unk

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OLUNTARY reporting th professionals of adverse ts and product problems

Form Approved:	OMB	40.	0310-0291	Expires:	12/31/94
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FDA Use Only (MS)

Triage unit	7	4	4	3	38	

Page	ofCOE**	
HE FDA MEDICAL PRODUCTS REPORTING PROGRAM		
A. Patient information	C. Suspect medication(s	
Patient Identifier 2. Age at time 3. Sex 4. Weight	Name (give labeled strength & mfr/label	gr, 11 NiOWII)
of event: 44 laterale - the	1 tsprin	
Date I male	12 Matrin PRN	
in confidence of birth:	2. Dose, frequency & route used	3. Therapy dates (if unknown, give durition)
B. Adverse event or product problem	11/1/1/1/1/1/1/1/1/1/1/1/1/1/1/1/1/1/1/1	Irom/lo lor best estimate) #1
1. Adverse event and/or Product problem (e.g., defects/matfunctions)	" 6 take danky	
2. Outcomes attributed to adverse event	12400m X1-2 Fid	12 -> 10/19/11
(check all that apply) congenital anomaly	4. Diagnosis for use (indication)	5. Event strated after use stopped or dose reduced
death	" minsaine	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
life-threatening permanent impairment/damage		#1]yes no doesn't
hospitalization – initial or prolonged	#2 mysames	#2] yes no doesn't
	1	ate (it known)
3. Date of event (D (9/D) 4. Date of this report	#1 #1	8. Event reappeared after reintroduction
(morden/yr) (managyyr)	#2 #2	#1 []yes [] no [] doesn't
5. Describe event or problem	9. NDC # (for product problems only)	
abd. pain MEG	- 1100 # (10) product production 5:177	#2 yes no doesn't
Coffee grounds evered	10 Concomitant medical products and	therapy dates (exclude treatment of event)
	To: Contosmant mesics. press.	
11 sain MEG		
aba. p		
2220		
given PRBC		
914-00	D. Suspect medical dev	ce
	1. Brand name	
1 17 ulcose en	2. Type of device	
EGO showed Zalcere in		4. Operator of device
duodenum.	3. Manufacturer name & address	health professional
		lay user/patient
anodenum.	1	other:
NSA 105 + ASA were Oct .	1	culei.
NSA 195 + ASA WELLOW !	RECEI	VFD
1. 371	NEOL!	
	6. NAV 9.0	2001
	model # MAY 2 9	
6. Relevant tests/laboratory data, including dates	catalog #	7 If implanted, give date
	MEDWAIC	7F1 010
HCT 26 on admission dropping to 22	serial #	8. If explanted, give date
1 1 4 22	lot #	(morday/yr)
droughing 18 66		
	other # 9. Device available for evaluation?	(Do not send to FDA)
		eturned to manufacturer on
		nd therapy dates (exclude treatment of event)
	10. Concomizant madical products un	
and the second the sec	[
 Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) 		
lade, programmy	E. Reporter (see confider	ntiality section on back)
	1. Name, address & phone #	
	VA HOSPITAL (119)	
	7400 MERTON MIN	
	SAN ANTONIO, TX	
1 1111778	2. Health professional? 3. Occupi	ation 4. Also reported to
C11/14930	yes no Pharr	manutachiret
Mail to: MEDWATCH or FAX to: 1-800-FDA-0178	5. If you do NOT want your identity	Userraciny
5600 Fishers Lane 1-800-FDA-0178 Rockville, MD 20852-9787	5. If you do NOT want your identity the manufacturer, place an "X"	In this box.
		oduct caused or contributed to the event



OLUNTARY reporting

Form	Approved:	QWB	Ng.	0510	0281	Expires:	12/31/9	4
			San	- (246	i mai	ement or	revers	

FDA Use Only (MB) Ith professionals of adverse Triege und its and product problems THE FDA MEDICAL PRODUCTS REPORTING PROGRAM _ of _ C. Suspect medication(s) Patient information 1. Name (give labeled strength & mfr/labeler, if known) 4. Weight 1. Patient identifier 2. Age at time of event: lemale Of Date **Male** 3. Therapy dates (if unknown, give durition) kgs of birth: Adverse event or product problem Product problem (e.g., defects/malfunctions) Adverse event and/or **#**2 Outcomes attributed to adverse even 12 disability Event abated after use (check all that apply) 4. Diagnosis for use (indication) stopped or dose reduced congenital anomaly death required intervention to prevent #1 ___yes __ no ___doesn't permanent impairment/damage life-threatening #2 #2 Tyes no hospitalization - initial or prolonged 7. Exp. date (if known) 6. Lot # (if known) 8. Event reappeared after Date of 3. Dete of reintroduction this report event (meldeylyr) 111 #2 #2 #1 yes no doesn't 5. Describe event or problem 9. NDC # (for product problems only) Melena, ! hemalemesis Solicylate tox: city, M5 change #2 yes no doesn Concomitant medical products and therapy dates (exclude treatment of event) D. Suspect medical device 1. Brand name 2. Type of device Ciperator of disvice 3. Manufacturer name & address health professional lay user/patient SALICYL other: SPEC RECEIVED 11/13/2000@03:45 Expiration dinte 5.2 MAY 2 9 200 SER 11/11/2000@13:31 25.4 if implanted, give date PLA catalog # 11/11/2000@04:38 31.0 H* SER If explanted, give data 11/10/2000@18:30 38.3 H* SER 11/10/2000@10:45 other # (Do not send to FDA) 9. Device available for evaluation? 46.8 H* SER returned to manufacturer on __ 11/10/2000@07:15 10. Concomitant medical products and therapy dates (exclude treatment of event) 49 H* SER E 11/10/2000@05:00 i.g., allergies, 50.0 H* SER F 11/10/2000@03:25 E. Reporter (see confidentiality section on back) 53.3 H* **SER** Name, address & phone # A 11/09/2000@18:50 VA HOSPITAL (119) 64.4 H* SER 7400 MERTON MINTER BLVD. SAN ANTONIO, TX 78284 2. Health professional? 3. Occupation 4. Also reported to manufacturer Pharm I yes no user facility or FAX to: MEDWATCH If you do NOT want your identity disclosed to distributor

5600 Fishers Lane Rockville, MD 20852-9787

1-800-FDA-0178

the manufacturer, place an " X " in this box. at personnel or the product caused or contributed to the even e VOLUNTARY reporting health professionals of adverse events and product problems

Form Approved: CM8 No. 0910-0291 E: pires:12/31/94 See OM8 statement on reverse

FDA Use Only

Triage unit	/	(44	L	4	4	:3	

A. Patient informati	on			C. Suspect med		i i
Patient identifier 2. Age at till Age at till Age at till		3. Sex 4. We	eight	Name (give labeled stren		
of event:	70		57 lbs	#1 aspirin 3	25 mg	
Date		male	or	#2	J	
In confidence of birth:			kgs	2. Dose, frequency & route	used 3. Therapy da	tes (if unknown, give curation)
B. Adverse event or				#T T QD	from to for best #1	estimate:
1. Adverse event and/or		(e.g., defects/malfund	tions)	1 00		
Outcomes attributed to adver (check all that apply)	disability			#2	#2	
death	congenita	l anomaly	1	4. Diagnosis for use (indica	ition)	 Event abated after use stopped or dose reduced
(morday/yr)		ntervention to preven		*1 preventation	e therasy	
hospitalization – initial or pr	· ·	t impairment/damage	e	#2		#1 Tyes no doesn
[V] HOSPITALIZATION — WIRTHAN OF PR	olonged other			6. Lot # (if known)	7. Exp. date (if known)	#2 yes no doesn
3. Date of	4. Date of	1/10/01		#1	#1	8. Event reappeared after
event II/IG/CO	this report	17 1-14.				reinfroduction
5. Describe event or problem	Das Cill	+ 61 Capli	n ŝi	#2	#2	#1 yes no doesn
Patient presented to	The Hollowick sty	p1, -70 Teen	(5)	NDC # (for product problet	ms only)	
light-hieded x a ma	inths fire di no	ed been an	(באורקט		-	#2 yes no doesn apply
ionsistently. He adv	when to weaken	iss of 2016 u	المالطان	10. Concomitant medical p		exclude treatment of event)
less in last 6 mor	ighs. He had b.	een taking o	an			
adult aspirin dail	nor the ods	ice of his	:	nifedipine 90m		
adult aspirive out	g per his care			terazosin 10mg	Q (I)	
local M.D. He res	seived 2 umas	64 01004	ch]			
advantation. EGD, re	with from lo	ail M.O., st	rcii el	D. Suspect medi	cal device	<u>.</u>
Childres Ston, Doo, 18	Journal .		-	Brand name		
antral ulcer	•			2. Type of device		· · · · · · · · · · · · · · · · · · ·
			j	2 Manufactures and 8 and		1 Constant of device
				3. Manufacturer name & ad	aress	4. Operator of device
			ļ	RF	ECEIVED	health professional lay user/patient
						other:
				1	MAY 2 9 2001	
				6. NACT	WATCH CTU	5 Expiration date
				model #WIEL	JAAU LOLLOLG	
3 Relevant tests/laboratory data	_			entalog #		7. If implanted, give date
Het 31,0 (37-50)	(11-16-00)			catalog #		- Indiday /*-
Hab 10.2 (12-17)			ļ	serial #		-
1190 10.5 CM				lot #		8. If explanted, give date
				other #		
			[9. Device available for evalu	uation? (Do not sen	d to FDA)
				yes no	returned to manufac	turer on
			ı	10. Concomitant medical pr	oducts and therapy dates to	exclude treatment of evant)
7. Other relevant history, includi			gies.			
race, pregnancy, smoking and a	· .	·				
HTN	Signationer	smoking hx	• ,]		confidentiality section	on back)
emphysemic	No alcohol	abuse in pass	st, Dad	1. Name address & phone	#	
GERD		H years.		PAMC		
BOH		1		1030 Jefferson	Acc #/19	
es, hayed strictu	٠ć			Memphis, To	33164	
C Tilludial	7			2. Health professional? 3.	Occupation	4. Also reported to
CIVITTY!	MATCH.	Or 54V :-			Pharmacist	manufacturer
	OVVATCH O Fishers Lane Isville MD 20852-9787	or FAX to: 1-800-FDA-017	8	5 If you do NOT want you		user factity distributor



LUNTARY reporting h professionals of adverse luct problems

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y (1 ' ' -	
-	

DA Use Only	
i riage unit	

3729459-X-00-01	s and product
HE FDA MEDICAL PRODUCTS REPORTING PROGRAM	Page of

A. Patient in	nformation			
. Patient identifier	2. Age at time		3. Sex	4. Weight
. 5504	of event:		lemale	t bs
In confidence	of birth:		male	kgs
B. Adverse	event or proc	luct proble	m	
1. Adverse ever	nt and/or 🔲	Product problem	(e.g., defects/n	nalfunctions)
 Outcomes attribution (check all that app 	ited to adverse event ly)	disability		
death		congenita		
life-threatening	(mořdayřyr)]	required in permanen	ntervention to p 1 impairment/d	orevent amage
hospitalization	- initial or prolonged	other:		
Date of event 3/1	401	4. Date of this report	5/14/	01

81 YOAAM adm for OSH for prolonged CP s/p AAA repair on 2/19. Complicated hospital course. On 3/16, blood in stool and Hgb decrease from 10.2 to 5.5 in 24 hrs. ASA D/C'd. Endoscopy revealed erosions on duodenal bulb and lower stomach. Pt. transferred to MICU. H.Pylori neg. On 3/18, Hgb again decreased from 12.1 to 8.2. Pt. had received daily ASA for a month before bleeding first noted. Likely cause felt to be NSAID in combination with other stressors. Hgb stable around 10 as of

Relevant tests/laboratory data, including dates

. Describe event or problem

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MAY 2 9 2001

MEDWATCH CTU

Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NKDA

PMH: AAA, CRI, COPD, GERD, GGPD

<u>CTU 144390</u>



5600 Fishers Lane Rockville, MD 20852-9787

or FAX to: 1-800-FDA-0178

C. Suspect met	<u> Aleguonii</u>	S)	
Name (give labeled stre			
*1 Aspirin			
#2			
2. Dose, frequency & rou	te used	3. Therapy da	ates (il unknown, give duration)
11 325 mg Pi	0 gd	iousto for pest	- 3/18/01
#2	0	#2	
4. Diagnosis for use (indic	cation)	L	5. Event abated after use
*1 prophylax	is, MI		stopped or dose reduced
#2			#1 yes no doesn'
6. Lot # (if known)	l l	ate (if known)	#2 yes no doesn'
#1	- #1		Event reappeared after reintroduction
#2	#2		#1 yes no doe sn't
NDC # (for product proble	ems only) -		
0. Concomitant medical j	products and	therapy dates (c	#2 yes no doe;n't appi'y
albuteral de	ocusare	mom	
amio te	2504	ornepre	apole
amio fe	ριαλορί	um predu	usone
airiucem 1	R WYW X	<u>x</u>	
D. Suspect med Brand name	icai uev	ce	
. Type of device			
. Manufacturer name & ac	ddress		4. Operator of device
•			health professional
			lay user/patient other;
			U vuici.
— ·	, A ²		5. Expiration date
ordel #	. :		5. Expiration date
odel#			-
stalog #			7. If implanted, give dute (mo/dayly:)
erial #			
1#			8. If explanted, give date (mortaly)1)
ther#			
Device available for eval		(Do not send	•
yes no		urned to manulaci	(mother-bet)
). Concomitant medical p	roducts and	therapy dates (e	exclude treatment of event)
E. Reporter (see	confident	iality section	n on back)
Name, address & phon			harmD
Hospital de Department	Chl. name		
Department	of Pharmac Street -	y Services	
	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	,	
Health professional? 3.	Occupatio	en n	4. Also reported to
yes no	Pharmacis	st	manufacturer
If you do NOT want you	r identity dis	Closed to	user facility
the manufacturer, place	: an " X " in t	his box.	distributor

J.

DLUNTARY reporting h professionals of adverse s and product problems

Form Approved:	OMB No	. 0916-0291	Expires:12/37/94

144410

#3/29488-0-00-01 +	s and produc		
ME EDA MEDICAL DRODUCTS REPORTING PROCESS	_		

			C			<u> </u>
THE FDA MEDICAL PRODUCTS REPORT	ING PROGRAM	Page	or _ COHE JE	ή¢.	<u> </u>	
A. Patient information			C. Suspect medi	cation(sl la	
Patient identifier 2. Age at time	3. Sex 4	4. Weight	Name (give labeled stren			
5495- of event: 75	female	ibs	*1 ASA	•		
bate of birth:	male	or				
III COMMOCINE		kgs	#2 Wuyaum 2. Dose, frequency & route	urad	2 Thomas	- A
B. Adverse event or produ			-	USEQ	POTIVIO (or bes	•
Adverse event and/or Pro Outcomes attributed to adverse event	oduct problem (e.g., defects/me	alfunctions)	*1 85 mg		*1 3/3	31-4/9/01
(check all that apply)	disability		#2 2.5/5 mg a	Ut.	#2 3/3	31-4/9/01
death	congenital anomaly		4. Diagnosis for use (indica			5. Event abated after use
life-threatening	required intervention to propermanent impairment/dar	revent	* Alib			stopped or dose reduced
hospitalization – initial or prolonged	other:	mage	#2 Alib			#1 yes no doesn'
	1 Date of		5. Lot # (if known)	7 Exp. d	ate (if known)	#2 yes no doesn'
event 4 9 01	this report 5/14/0)	1 1	#1	#1	are (ii kilowii)	8. Event reappeared after
5. Describe event or problem	(makkeyiyri) 3 17 01		#2	#2		reintroduction
		1 L	. NDC # (for product problem	_[#1 yes no doesn't
			- 1400 # (IOI product problem			
TE VOV found at homein		1	0. Concomitant medical pr	oducts and	therapy dates (e	#2 yes no doe:n't app:y
75 YOM found at home in p aspirin. Pt brought to OSH	ER on 4/9 with	11	Metoprolol Manihidenie Amiodarane	capto	pril	and the state of every
INR=11.7, Hgb=8.9. Gastri	c lavage was (+) for	11	ranihideria	amon	cicillin/cl	avo ana la
blood. EGD on 4/10 reveals lesion of the duodenal bulb	ed an arterial vessel	11	amiodamo	Walfe	zvin	acto (a) (a)
secondary to aspirin. Pt als	o on warfarin					
2.5mg/5mg_po QD alternati	ing. Warfarin most		D. Suspect medic	cal devi	ce	
likely exacerbated the situate from OSH since ICU beds for	tion. Pt transferred	'	Brand name			
units of PRBCs and FFP on	4/9-4/10. (+)	2.	. Type of device			
melena. Upon transfer, Hgt	p=6.1. On 4/13,	1 3	Manufacturer name & add	Irace		7.
Hgb=9.1		11				4. Operator of device
						health professional lay user/patient
<u> </u>		J 1				other:
						-
		1 L				5. Expiration date
		6.				(mordayiyi)
Relevant tests/laboratory data, including data	es	m'	odel #			-
High 6.1 8.1 9.8 9.5	. 4/z	Ca	talog #			7. If implanted, give date (mordayly)
Hap 6.1 8.1 90 00			rial#			
7.5	11 RECE	EINED	*			8. If explanted, give dute
		11.	=			_ (moldeylyr)
	MAY 2		her # Device available for evalu	stion?	(D)	
	MEDIMAT	11	yes no	_	Do not send) Thed to manufact	
	MEDWAT	CHUH	Concomitant medical pro	•		
		1 1	pi c	POUCES EING (rierapy oates (e.	xoude treatment of event)
Other relevant history, including preexisting race, pregnancy, smoking and alcohol use, hep	medical conditions (e.g., all Datic/renal dysfunction, etc.)	lergies,				
	Systematically city					
NKDA		١	. Reporter (see co	onfidenti	ality section	on back)
PMH: AAB, HTN, TIA, aut	hitis Bladdy at	mu '	Name, address & phone		y, Pł	armD
Urosepsis		۱ ۱ ،	Hospital Charles	r DL		
م در په کې که			Department of	Pharmacy Street -	Services	Í
		11				
C-TW-144410)	2.	Phone:	Occupanór	<u>, </u>	4. Also reported to
Mail to: MEDWATCH	or FAX to:	[1	•	-	manufacturer
5600 Fishers Lane	1-800-FDA-01	78	If you do NOT want your i	Pharmacis		user facility
Rockville, MD 208	152-9787]	the manufacturer, place a	n " X " in th	is box.	distributor



MED	X AT	ĊН

for VOLUNTARY reporting by health professionals of adverse events and product problems

Form ∆p	************	MB Ha.	212-1271	Espiron: 1	201/-
FOA Use Cinty (phila pint deal i	
Triage unit	7.	1.71	11.1	F77	

THE FUL MEDICAL PRODUCTS REPORTING	PROGRAM	Page 1	a 1 /	_ &	<u> </u>	1 100
A. Patient information			C. Suspect m	or leading	(c)	
1. Patient identifier 2. Age at time	3. Sex 4.	. Weight	Name (give labeled :			
XX of event: SSYR	female	ibs		/ <i>N</i>		
Date of birth:	p male	or	12 / / / /		EAS	
B. Adverse event or product	1 — 1	kcj8	Dose, frequency & r	and used		ites (if unknown, give curation)
	z problem (e.g., delects/mal	tunctioner	71	•	from the sor best	e-umana)
Outcomes attributed to adverse event (check all that apply)	disability		02			
death	congenital anomaly	[] .	I. Disgnosis for use (ir	idication)	42	5. Event abated after use
life-threatening	required intervention to pre-	event	#4	,		stopped or dose reduced
- Aospitalization - initial or prolonged	permanent impairment/dan other:	- 11	#2			#1 Dyes One Ogesh
		ìL	Let # (if known)	7. Exp.	date (il known)	#2 yes no desn'
event 2~10~0/	ale of this report 5-29-	1 1	#1 ·	#1		5. Event reappeares after
5. Describe event or problem	ordayarin 5 C	~/	12	#2		reintroduction
		 	. NDC # (for preduct pre	blems only)		#! yes no []doesn't
·		1 1	-	-	1	#2 yes no gesor
:			o. Concomitant medic	al products an	d therapy dates (e	exclude (earment of event)
GASTROINTESTINAL BLEED: MELE	NA. Patient taking Aspir	rio &				
I SOUND TO THE PROPERTY OF THE PARTY AND THE PROPERTY OF THE PARTY OF	BOYGO OF PRAISON A ASIA SISS	zy.				,
Came to hospital where H/H stable at multiple linear erosion in antrum & 1cm	Man beard	11				
Tabonation point. Little: DG: MSVID IUQUO	ed gastric ulcers. To be	. F/U	D. Suspect me	dical dev	(CE	
in clinic.	-		Brand name			
		 ₂	Type of device			
			Manufacturer name 4			T
			Martin and Control of a constant of	4041C75		Cperator of device health professional
			RI		/	lay user/patient
		11	1.11	ECE	VED	other:
		[]				
		6.		1AY 3 0 ;	2001	5. Expiration date
		1 1 "	odel # MEDI	MATA		(marasyny)
 Relevant usis/laboratory data, including dates 			talog #	WATUR	CTIT	7. If implanted, give date
	•	11				(mordayeye)
			rial #			
		lot	· · · · · · · · · · · · · · · · · · ·			8. If explanted, give date (modulyly)
			ner #			
		8.	Device available for ex		(Do not sand	· · · · · · · · · · · · · · · · · · ·
					med to manufactu	(moldante d
			Cancomitent medical	products and	therapy dates (ex	cinde trestment of event)
Other relevant history, including preexisting a race, pregnancy, smoking and alcohol use, hepal	redical conditions (e.g., ali	orgies,	•			
The state of the s	derenal dyslunction, etc.)	1 _				
			. Reporter (see	confident	ality section	on back)
		11'-	Name, address & pho	ne #		
		4			^	DSS
			- N	LED CT		
was An				Sτ	Rm 🖷	MAY 3. 0 2001
CTV144480		2. 1	lealth professional?	3. Occupation	14	. Also reported to
Mail to: MEDWATCH	or FAX to:		⊠yes □ no	0	اسيري	manufacture
5600 Fishers Lane	1-800-FDA-01	ســـا		PHARMA	M21.	user facility
Rockville, MD 2085	2-9787	Ju.	If you do NOT want yo	ur identify disc	losed to	distributor
		L	the manufacturer, plac	æan 🏋 in th	is bax, 💢	C ORGUNOTOS

FDA Form 3500 (4/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the Event.

MAY 2 9 2001



For VOLUNTARY reporting by health professionals of adverse events and product problems

THE FOA MEDICAL	L PRUDUCTS REPOR	TING PROCE		Page _	<u> </u>				
	nformation				C. Suspec	t medical	tion(s)		
1 Patient identifier	2. Age at time of event: 5/	/9	3. Sex	4. Weight	1. Name (give lat	•	mirriabeler, if	known)	
×χ	Date	- Ne	lemalo	or Ibs	A	Spilm			
in confidence	of birth:		(Printe	—— kgs	2. Dose, frequen	TV & route ware	d 3. Th	BEROW dates	s (if unknown, give duration)
1. Adverse eve	event ar prod				#1	cy a route used	for #1	mito ici besi esii	water
2. Outcomes attrib	theve belevbe of bell	roduct problem		manunchons)					
(check all that app	pty)	disability	ai anomaly		42 4. Diognosis for	use (indication)	*5	15	Event abated after use
death	(maidapiye)	required	intervention to	prevent	#1	(stopped or dose reduced
1 =	n – initial or prolonged	permane ather;	int impairment/	lamage	#2	······································	.,		" Dyna Do Depen
3. Date of		4. Date of			6. Lot # (if known)	7.	Exp. date (if)	known) "	12 yes no dogsn
event 2	-14-01	this report	5-29	7-0/	<u> </u>		l	8	. Event reappoared after
5. Describe event a	r problem				*2	H2	2		reintroduction 1 [yes no] ggest
					9. NDC # (for prod	uct problems on	nly}	-	
	•				10. Concomitant	medical produc	ets and theram	u dales leve	2 yes no Jappiy
Mixed w/ sto Also vomited about 9, EG	HEMATEMESIS & P to QID x 1 year b/o h pol x 5 over the last 5 d blood x 2 on day pr all b showed antral ulc injected. Patlent's H or d/t NSAID.	eadache carr hours, c/o di for to coming or w/ small ve	e to hospital o Zzy while star to hospital. H	c/o BRB iding. Ibg in ER	D. Suspec 1. Brand name 2. Type of device	t medical	device		
					3. Manufactures n	ame & address	····		4. Operator of device
					!	RECE	EIVE	D	health professional lay user/patient other:
					Ġ.	WAY 3	0 2001		5. Expiration date
6. Relevant teats/let	poratory data, including	dales			model #	EDIA/AT	CU OT	·	
					catalog #IVII	-DVVAI	<u> </u>	<u>U </u>	7. If implanted, give date mudayyri
					for #				B. If explanted, give date (markeylyr)
				,	9. Device available yes	no [? (Do returned to r	not sand to manufacture	ır on
					10. Concomitant n	redical product	s and therapy	dales (exdu	ide treatment of event)
 Other relevant his race, pregnancy, st 	tory, including preexit moking and alcohol use	iling medical o , hepatic/renal o	onditions (e.g. lyslunction, etc.	, allergies,					
					E. Reporte	r (see canfi	dentlality s	естіоп а	π back)
					1. Name, address	MES		m T	DSS 3 0 2001
CTV144	1487				2. Health profession	nal? 3. Occi	noitsqu	a. ;	Also reported to
SID A Mai	il to: MEDWATCH	Lane	7 FAX to: 1-800-FDA	-0179		no PHAI	RMACIS	T [manufacturer
	Rockville, MD		TOVER		5. If you do NOT with the manufacture	rant your identi er, place an " X	ty disclosed to the state of th	" X	distributor

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event. MAY 2 9 2001

FDA Form 3500 (8/93)



THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

HE FUN MEDICA	/ ROBUCTO III			
. Pattent II	oformation 2. Age at time		3. Sex	4. Weight
	of event:	62 yrs	☐ temale	tbs
	or — Dete			or
in confidence	of birth:			94.5 kgs
	event or pr	oduct prob	olem	
🔀 Adverse eve			roblem (e.g., defec	:ts/malfunctions)
Outcomes attribute (check all that apply	ed to adverse event	dis	ability	
52 10/	17/2001	cor	ngenital anomaly	
∠ death	(ma/day/yr)		uired intervention to	
ife-threateni	-		manent impairmen	l/damage
i hospitalizati	on - initial or prolo	onged oth	er:	
Date of event (modspyr)	9/17/1999	4. Date this (more)	report 05/22	2/2001
Describe event or	problem			
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			received f	
			ial "Antit	
			of Hemodia	
			dy from th	
			ive Studie	
)). Sanofi-	
			reported	
			urer Case	
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			nelabo Inc.	
			ose patient	
_			s while be	
		clopido	grel/aspiri	n
combin	ation.			
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	t 549-04 /			t Two: A
			with Plavi	
(clopi	dogrel) an	nd aspiri	n experienc	ed CAD *
Relevant tests/lab	oratory data , incl	uding dates		
N7*				
NI				
		ovieting modical	conditions (e.g. of	lergies race
 Other relevant his pregnancy, smoki 	story, including pre ing and alcohol use,	hepatic/renal dys	function, etc.)	lergies, race,
	-			
	ears sinc			
Concor	itant dis	ease(s):	Congestive	heart
failur	e, Hypert	ension		
				antitute on
-D A			ort does not col ical personnel, t	
=	aomiss	non mai med	icai pei suillie). (JOSE TOURNEY,

	Or Date		M male	or	#2 Aspirin			
in confidence	of birth:			94.5 kgs	2. Dose, frequency & route	used	3. Therapy date	s if unknown give
	event or produ			1 11 11	#1 75 mg QD PO		#1 NI to	
Adverse ever		Product prob	lem (e.g., defect	s/mailunctions)	205 00 00		#2 NI to	NIT
Outcomes attributed (check all that apply)		disabi	lity		#2 325 mg QD PC 4. Diagnosis for use (indica		#2 NI to	5. Event abuted
X death _10/	17/2001	conge	nital anomaly			ilion,		or dose nadu
life-threatening	(mo/day/yr)		ed intervention to inent impairment/		#1 "			#1 yes
	on - initial or prolonged		ment impannene	damago	#2 *			#2 VES
nospitalizatio	on - unuar or prototiged				6. Lot # (if known)		date (if known)	, yes
Date of	9/17/1999	4. Date of this rep	ort 05/22	/2001	#1 NI	#1 NI		8. Event reapport
(mo/day/yr)		(mo/day/yr			#2 NI	#2 NI		#1 yes
Describe event or p	meldoru			ļ	9. NDC # - for product probl	ems only (if knov	vn)]
The fol	lowing repor	t was re	eceived fr	om the	#1 NI	#2 NI	:	#2 [] yes
	ored VA-CSP				10. Concomitant medical p	roducts and th	erapy dates (exclud	e treatment of ever
Agents	in the Preve	ntion o	f Hemodial	ysis				
	Thrombosis, "				Name: EPOGEN Dat	es:		
	as Affairs Co			Program	Name: Fosinopril		_	
	cted under a				Name: Folic acid	Dates:	*	
	labo Inc. ini				G. All manufac	cturers		. ,
	s trial in Ma				1. Contact office - name/a	ddress (& mfrin	g site for devices)	2. Pho
	A01454. The b				Sanofi-Synthelal	oo Inc.		(212
	2001, Sanofi				90 Park Avenue	016		3. Rep (che
	se reports fr				New York, NY 10	010		
	enced adverse							
treated	d with the cl	lopidogr	el/aspiri	1				
combina	ation.							
								区
	t 549-04 / Ir		Visit		4. Date received by manuf	acturer 5.		
	r-old male to				(mo/dsy/yr) 05/11/2001	(A)NDA # 20-83	<u> </u>
(clopic	dogrel) and a	aspirin	experience	ed CAD "	03/11/2001		IND#	
5. Relevant tests/lab	oratory data , including o	dates			6. If IND, protocol #		PLA #	
NI							pre-1938	yes
					7. Type of report		отс	
					(check all that apply)		product	yes
					5-day 🗵 15-day	8.	Adverse event ten	⊥ ==:: m(s)
					10-day periodi	c c	ORONARY ART	ERY DISCRIM
						⊔p# E	VENT, SEPSI	s, cardiac
						D	UODENAL ULC	
7. Other relevant his	story, including preexisting and alcohol use, hepa	ng medical con	ditions (e.g., alle	ergies, race,	9. Mfr. report number		7 6 /	A 4 4
pregnancy, smoot	ng and action use, heper	uciterial dysion	,uori, c.o.,		T200100274			
Four y	ears since l	ast smo)	ced.		E. Initial repo	rter		
Concom	itant diseas	e(s): Co	ongestive	heart	1. Name, address & phor	ne #		
failur	e, Hypertens	ion				*	ge 👊	· 46
					Boston Universi	3 5	71.5	9
					Boston VA Medic			
					150 South Hunti	ington Ave	. # 	
	Submission	of a report	does not con	stitute an	2. Health professional?	3. Occup	nation	4. Initial repo
	admission t	that medica	il personnel, u	ser facility,	l	J. Occup	JuliVII	ser t repor
ニレス			rer or product		yes Lino	STUDY	CHAIRMAN	yes
Comain Facsimile of	contributed item com	i to the ever pleted on co	nt Intinuation page	s.				

ıthelabo Inc.

1.00roned by FDA on 3:22 94 Domain Facsimile
Mir report #
T200100274 UF/Dist report #

1 of 2			FDA Use Chly
C. Suspect medica	tion(c		
Name (give labeled strength & m			
PLAVIX			i
Aspirin			
Dose, frequency & route used		3. Therapy dates from/to (or best estimate)	if unknown give duration)
75 mg QD PO		#1 NI to N	
325 mg QD PO		#2 NI to N	I
Diagnosis for use (indication)		} :	Event abuted after use stopped or dose reduced
*			l1 yes no doesn't
			apph
Lot # (if known)	7. Exp. d	late (if known)	yes no doesn't apply
NI	#1 NI		Event reappeared after reintroduction
NI	#2 NI		#1 yes no doesn't
NDC # - for product problems or	nly (it know	n)	appl/
NI	#2 NI	'	#2 yr:s no doesn't appl /
). Concomitant medical product	s and the	rapy dates (exclude t	reatment of event)
ame: EPOGEN Dates: ame: Fosinopril Dat			
ame: Folic acid Dat		•	
G. All manufacture Contact office - name/address		site for devices)	2. Phone number
anofi-Synthelabo I	nc.		(212) 551-4000
0 Park Avenue			3. Report source
ew York, NY 10016			(check all that apply)
			ii foreign
			l
			consumer
			X health
. Date received by manufacture	r 5.		professional
(mo/day/yr) 05/11/2001	(A)	NDA # 20-839	user facility
05/11/2001	1	ND#	company representative
. If IND, protocol #		PLA #	distributor
		pre-1938 y	es other:
. Type of report (check all that apply)		OTC	200
5-day 2 15-day	l	product — 3	
	8.	Adverse event term(s)
10-day periodic			RY DISCRIPER, UNCODED
Initial follow-up #_		ENT, SEPSIS, ODENAL ULCES	CARDIAC ARREST,
3. Mfr. report number			in a right
r200100274		(* 3	<u>.</u>
E. Initial reporter			
1. Name, address & phone #			
	*	ړد خپ	**
Boston University	cheel.	of Medicine	
Boston VA Medical (
150 South Huntingto	AV 3	7. (X)	
2. Health professional?	3. Occupa	<u> </u>	4. Initial reporter also
🛛 yes 🗌 no	•	CHAIRMAN	ser t report to FDA
	~-~~		I DOST THE CHI



ofi-Synthelabo Inc.

A.1. Patient identifier

MED WATCH

identifier	G.s. wir. report in
	T200100274

G.9. Mfr. report number

T200100274

Page 2 cf 2

B.5. Describe event or problem

[continuation:] on 17 Sept 1999, kidney transplant (date unspecified), sepsis, and cardiac arrest on 17 Oct 1999. Randomization date was 11 January 1999. Descriptions of event read: "ESRD on dialysis" and "GI bleeding requiring transfusion, surgery involving cardiac arrest. Sepsis." Patient was hospitalized on 29 Sept 1999, and died on 17 Oct 1999. Primary reason: duodenal ulcer, hemorrhage. Secondary reason: septic shock.

Assessment of relationship to study drug by Investigator: Possible Same patient as T200100273.

Corrective treatment: transfusion, surgery.

C.4. Diagnosis for use (indication) (Suspect #1)

prevention of hemodialysis access thrombosis

C.4. Diagnosis for use (indication) (Suspect #2)

prevention of hemodialysis access thrombosis

C.10. Concomitant medical products and therapy dates (exclude treatment of event)

[continuation:] Name: MULTIVITAMINS Dates:

Name: Iron IV Dates: NI to NI

Name: TUMS Dates: Name: PHOSLO Dates:

Name, address & phone #

[continuation:]

UNITED STATES

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May 25 151

 $M_{W^{-1}V^{-1}} = \{i \emptyset\}$

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Synthelabo Inc.

	Approved by FDA on	/22/94
Domain Facsimile		
Mir report #		
T200100270		
UF/Dist report #		

Page	1	of	:
ayc	•	v.	*

ge 1 of 2				FDA Use Only
C. Suspect medica	tion(s)			PDX 05 CANY
Name (give labeled strength & m)		
#1 PLAVIX				
us landed				
#2 Aspirin 2. Dose, frequency & route used	3 1714	wany datus /i	unknovri, giv	en dumition)
#1 75 mg QD PO	fron	uto (or hest s-dima	(e)	30-MAR-1399
#2 325 mg QD PO 4. Diagnosis for use (indication)	#2			30-MAR-1 399
#1 *]	or dose red	d after use stopped uced
			1/es _	no do-sn't
#2 *			2	ylc qa 't'nae ob
6. Lot # (if known) #1 NI	7. Exp. date (if kr	· -	Eugat see	ap ıly
			Event reapprend	on
#2 NI 9. NDC # - for product problems onl	#2 NI		1 📋 Jes	inoldoesn't
#1 NI	#2 NI		2 yes	yic qathat obcn
10. Concomitant medical products		- Cavaluus tr		ylc ga
To: Oblivoring incorear products	and therapy date	s (excione in	amen (rez	erit.
Name: Lansoprazole Da	ates:			
Name: MINIMS ARTIFIC		ates:		
Name: NEPHROCAPS Date	es: *			
G. All manufacture	rs			
1. Contact office - name/address	(& mfring site for d	evices)	2. Pho	ne number
Sanofi-Synthelabo Inc	c.		(212) 551-4(00
90 Park Avenue				ort source
New York, NY 10016			1 -	ck all that apply) foreign
				study
			1 -	literature
				consumer
			\S \$	health
4. Date received by manufacturer (mo/day/yr)	5. (A)NDA # _	20-839		professional
05/11/2001				user facility company
6. If IND, protocol #	IND#_			representative
o. II II to, protoco; w	PLA#_			distributor
7 Time of second	pre-1938	yes		otner:
 Type of report (check all that apply) 	OTC product	yes		
☐ 5-day ☐ 15-day			_1	=======================================
10-day periodic	8. Adverse a			
☐ follow-up #	GI HAEMO			
23 minut		W. A. J	3 11	·
9. Mfr. report number				
T200100270				
E. Initial reporter				
1. Name, address & phone #	- New -	· ** 41		
		Section 1		!
Boston University Sch		licino		
Boston VA Medical Cer 150 South Huntington		*. *		
	TVI PA			i ;

A. Patient in	nformation			
stient identifier	2. Age at time of event:		3. Sex	4. Weight
	or —	59 yrs	female	NI Ibs
in confidence	Date of birth:		⊠ male	or NII kgs
B. Adverse	event or pro	oduct proble	m	
1. Adverse eve			lem (e.g., defects	s/malfunctions)
2. Outcomes attribute				
(check all that apply)	disabil	ity nital anomaly	
death	(mo/day/yr)	~	ed intervention to p	nrovent
ill life-threateni	ng		nent impairment/o	
hospitalization	on - initial or profo	nged 🔲 other:		
3. Date of		4. Date of		
event 0	3/30/1999	this repo	ort 05/22/	2001
5. Describe event or p	problem			
		port was re		
_		SP 440 tria		
_		evention of	-	ysis
1		s," a study		
Veteran	s Affairs	Cooperativ	e Studies	Program
(conduc	ted under	a VA IND).	Sanofi-	
. =		initially r	-	_
1		Manufactur		
1999USA	.01454. The	blind was	broken,	and on
11 May	2001, Sand	ofi-Synthel	abo Inc.	received
the cas	e reports	from those	patients	who
experie	nced adver	cse events	while being	ng
treated	with the	clopidogre	1/aspirin	
combina	tion.			
_			_	
Patient	541-05 /	Initials:		
A 59-ye	ar-old ma.	le, who beg	an Plavix	*
6. Relevant tests/labo	ratory data , includ	ing dates		
30 Marc	h 1999• #4	matocrit:	15 9	
			13.7	
7. Other relevant histo	ory, including preex	isting medical condi	tions (e.g., allergi	ies, race,
pregnancy, smoking	and alcohol use. h	epatic/renal dysfunction	on, etc.)	
previou	s history	of GI blee	d in Marci	h 1998
-	_	ase(s): Not		
CONCONIA	cane arbei	ibe(b). Not	reported	
		ion of a report d n that medical p		
FDA		r, manufacture		
D		ed to the event.	•	

Dumain Facsimile of FDA Form 3500A

Item completed on continuation pages.

2. Health professional? 🔀 yes 🗌 no

3. Occupation STUDY CHAIRMAN 4. Initial reporter also sent report to FDA



-Synthelabo Inc.

MED WATCH

T200100270 Pag = 2 cf 2

8.5. Describe event or problem

[continuation:] (clopidogrel) and aspirin on 12 February 1999, experienced a hematocrit of 15.9 and GI bleed on 30 March 1999. Patient noticed blood in stool on 30 March 1999. Hematocrit was 15.9 on that same day. Patient's hematocrit had been continually decreasing since initiation of study drug on 12 February 1999. No further information is available.

Outcome: Recovered

Assessment of relationship to study drug by Investigator: Possible

Corrective treatment: Not reported

C.4. Diagnosis for use (Indication) (Suspect #1)

prevention of hemodialysis access thrombosis

C.4. Diagnosis for use (indication) (Suspect #2)

prevention of hemodialysis access thrombosis

C.10. Concomitant medical products and therapy dates (exclude treatment of event)

[continuation:] Name: Iron Dates:

E.1. Name, address & phone #

[continuation:]

UNITED STATES

W: 12 3 1503

W. A

nthelabo Inc.

	Approved by FDM on 3-22 a
Domain Facsimile	
Mtr report #	
T200100268	
UF/Dist report #	·

Pag	ge 1 of 2				FDA Use Cinty
1	O Current medica	Nier-/			100000
	C. Suspect medica 1. Name (give labeled strength & m				
	PLAVIX	III/Japelei, I	, MIOHII		
	* * * * * * * * * * * * * * * * * * * *				
}	#2 Aspirin		T		
U	2. Dose, frequency & route used		from/to (or bes es	stuniate)	own: give duration)
	#1 75 mg QD PO		#1 NI to		
	#2 325 mg QD PO		#2 NI to	NI	
	4. Diagnosis for use (indication)				nt abilited after use stopped ose radiliced
П	#1 *			#1 [yes no doesn't
П	# 2				apph ves no doesn't
[6. Lot # (if known)		ate (if known)	72	y∈s
	#1 NI	#1 NI			nt reappeared after troduction
	#2 NI	#2 NI		! #1 <u> </u>	yes no doesn't
	NDC # - for product problems or	nly (if know	1)		appl ₁
	#1 NI	#2 NI		#2 (yes no doe:.n`t apply
	10. Concomitant medical product	s and the	rapy dates (exclud	e treatme	nt ct avent)
П					
	Name: Metoprolol Dat Name: Allopurinol Da				
	Name: Calcitriol Dat				
H					
	G. All manufacture 1. Contact office - name/address		site for devices)		2. Phone number
	Sanofi-Synthelabo I		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		(212) 551-4000
	90 Park Avenue				3. Report source
	New York, NY 10016				[check all that appl/)
					toreign
					i⊠ study
					l literature
11					consumer
	4 Date received by manufacturer	5.			i∆ health professional
	4. Date received by manufacturer (mo/day/yr)	(A)	NDA # 20-83	9	user facility
╛	05/11/2001	l l	ND#		company
	6. If IND, protocol #	F	PLA #		representative
		-	ore-1938	yes	= distributor
	7. Type of report		OTC T	,00	other:
	(check all that apply)		product	yes	
	5-day 🔀 15-day	B. /	Adverse event terr	n(s)	L ==
	10-day periodic	- 1			ORRHAGIC, GI
	☐ Initial ☐ follow-up #_		EMORRHAGE		+ p 3 .4
4	9. Mfr. report number		₩		•
	•				
	T200100268				
	E. Initial reporter		<u>.</u>		
	1. Name, address & phone #				
			206		
	Boston University S Boston VA Medical C		I medicin	•	
	150 South Huntingto		*		
ل		MA.	1. a 7.2		
	· ·	3. Occupat	ion		tial reporter also ent report to FDA
	yes no	STUDY (CHAIRMAN	[ves no unk

E FDA MEDICA	L PRODUCTS REP	PORTIN	G PROGRA	<u></u>	
Patient i	nformation				
stient Identifier	2. Age at time	-		3. Sex	4. Weight
	of event:	78	yr s	female	NI Ibs
in confidence	Date of birth:			Male Male	or NI kgs
	event or pro	oduc	t proble	m	
1. Adverse eve				lem (e.g., defect	s/malfunctions)
2. Outcomes attribute					
(check all that apply	<i>(</i>)		disabil	ity nital anomaly	
death	(mo/dayryr)			ed intervention to	prevent
life-threaten	ing			nent impairment/o	
M hospitalizati	on - initial or proloi	nged	other:		
3. Date of event (moldeyly)	05/26/1999		4. Date of this repo	ort 05/22/	/2001
5. Describe event or	problem				
The fo	llowing rep	nort	WAS TE	ceived fr	om the
	sored VA-C				
-	in the Pro				
1	Thrombosis				
1	ns Affairs				
1	cted under				
Synthe	labo Inc. :	init	ially :	eported a	summary
of thi	s trial in	Man	ufactui	er Case I	Œ
1999ps	A01454; The	e bl	ind was	s broken,	and on
11 May	2001, San	ofi-	Synthe]	labo Inc.	received
the ca	se reports	fro	m those	patients	who
experi	enced adve	rse	events	while bei	.ng
treate	d with the	clo	pidogre	al/aspirin	ı
combin	ation.				
Patien	t 689-02 /	Ini	tials (■: A 78-y	ear-old
male r	eceived Pl	avix	(clop:	idogrel) a	ınd
aspiri	n, and exp	erie	nced g	astric ulc	er *
6. Relevant tests/lab	oratory data , inclu	ding date			
	•	-			
NI					
i					
Ì					
ĺ					
7. Other relevant his pregnancy, smoking	story, including preeing and alcohol use, i	xisting i hepatic/r	nedical cond enal dysfunct	itions (e.g., aller ion, etc.)	gies, race,
No pri	or history	of	GI ble	ed. Had	
hypote	nsion upon	pre	servat	ion but re	sponded
to vol	ume replac	emen	t. Tak	ing Cimeta	adine
,	lactically	_			
Concom	itant dise	ase (s): Co	ngestive h	neart
failur	e, myocard	lial	infarc	tion, angi	ina, *
FDΔ			-	does not cons personnel, us	
: : //	0.01111291	J., LI10		For comment as	y;

Coman Facsimile of FDA Form 3500A

distributor, manufacturer or product caused or contributed to the event. Hem completed on continuation pages.



fi-Synthelabo Inc.

ED WATCH

A.1. Patient Identifier G.9. Mfr. report number T200100268

Page 2 of 2

B.5. Describe event or problem

[continuation:] hemorrhage and upper GI bleed on 26 May 1999. Randomization date was 24 April 1999. Description: He had awoke with vague abdominal discomfort, and vomited blood at 5:45 am. Came to Emergency Room at 7:00 am. Surgery date for gastroectomy was 31 May 1999. Patient was discharged 02 July 1999.

Outcome: Recovered 31 May 1999.
Relationship to study drug: Definite
Corrective treatment: Cimetadine and DDAVP; gastrectomy.

B.7. Other relevant history, including preexisting medical conditions (e.g., altergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

[continuation:] hypertension

C.4. Diagnosis for use (indication) (Suspect #1)

prevention of hemodialysis access thrombosis

C.4. Diagnosis for use (indication) (Suspect #2)

prevention of hemodialysis access thrombosis

C.10. Concomitant medical products and therapy dates (exclude treatment of event)

"continuation:] Name: Calcium acetate Dates:
.me: Folic acid Dates:

E.1. Name, address & phone #

[continuation:]

UNITED STATES

4.4

W. C. J. C. J.

MAN A P MAN

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THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

DLUNTARY reporting h professionals of adverse s and product problems

Internet Submission - Page 1

FDA Use Only

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A. Detienting	
A. Patient information	C. Suspect medication(s)
1. Patient Identifier 2. Age at time 3. Sex 4. Weight	Name (Product Name) (Labeled Strength) (Mfr/Labeler)
025947 of event: or female 235 lbs	#1 Lovenox /100mg /
Date	Ned with
In confidence of birth: kgs	#2 Aspirin / 325mg
B. Adverse event or product problem	2. Dose/Frequency/Route used 3. Therapy dates (if unknown, give duration)
	105mg / hid / From To (or hest estimate)
	#1 133mg / Subcutaneous #1 05/23/2001 - 05/30/2001
2. Outcomes attributed to adverse event (check all that apply) disability	#2 325 /qd /Orai #2 05/23/2001 ~ 05/30/2001
	4. Diagnosis for use (separate indications with commas) #4 anti platelet #5 Event abated after use stopped or dose reduced
required intervention to prevent permanent impairment/damage	[] []
	#2 anti platelet #1 / yes no doesr apply
hospitalization – initial or prolonged other:	#2
3. Date of 4. Date of	6. Lot # (if known) 7. Exp. date (if known) #2 vyes no doesii apply
event 05/30/2001 this report 06/04/2001	#1 #1 8. Event reappeared after
(mm/dd/yyyy) 5. Describe event or problem	reintroduction
· · · · · · · · · · · · · · · · · · ·	#2 #2 #1 Tues Tar Tidoscu
Patient receiving Lovenox and ASA	9. NDC # (for product problems only) #1 yes no doesn apply
developed a GI bleed which required transfusions of blood	#2 yes no doest
cransitisions of plood	10. Concomitant medical products and therapy dates (exclude treather Lof event)
	To. Concomitant medical products and therapy dates (exclude treatment of event)
	D. Suspect medical device
	1. Brand name
	2. Type of device
	3. Manufacturer name & address 4. Operator of device
nce	health professional
DSS	
iliki o oon	cther:
JUN 0 6 2009	JUN 0 5 2001
	3014 0 3 2001
	6. Superation date (mm/diutyyyy)
	model # MEDWATCH CTU
Relevant tests/laboratory data, including dates	
• • • • • • • • • • • • • • • • • • •	catalog # 7. If implanted, give date
	(Controlling
	serial #
	lot # 8. If explanted, give date
	(mm/autyyyy)
	other#
1	Device available for evaluation? (Do not send device to Ff.A)
	yes no returned to manufacturer on
1	(cont/dd/yyyy)
	10. Concomitant medical products and therapy dates (exclude treatment of event)
Other relevant history, including preexisting medical conditions	
.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.	
	E. Reporter (see confidentiality section on back)
	1. Name phone #
<u> </u>	
JUN - 4 2001	Rd Medical Center Pharmacy,
, 2001	1.02
	United States
(TV144796	2. Health professional? 3. Occupation 4. Also reported to
	Dhomasid.
Mail to: MEDWATCH or FAX to:	That active
5600 Fishers Lane 1-800-FDA-0178 Rockville, MD 20852-9787	5. If you do not want your identity disclosed to User facility the manufacturer, place an "X" in this box.
	The state of the s

Form Approved: OMB No. 1910-0221 Expires: D4/30/03 For use by user-facilities, See OME statement on reverse Wir report # distributors and manufacturers for MANDATORY reporting VEATING money REPORTING PROCEAM Page ____ of / A Patient information C. Suspect medication(s) 4, Weight 1. Name (give Speled strength & mir/labeler, if known) ___ female Date of birth: 6 Co kgs V male VIORE Thorapy dates (if unknown, give duration) B. Adverse event or product problem 1. Advorse event and/or Product problem (s.g., defects/majtunctions) Outcomes altributed to adverse event (check all that apply) death _ congenital anomaly 4. Diagnosis for use (indication) Event at stad after use stopped or dose reduced Ilfo-breatening required intervention to prevent permanent impairment/demage Management of the second secon #1 yes no docant #2 Jes Juo Jace su 8. Let # (if known) 8. Event reappeared after reintroduction Jyos Dno Depent 9. NDC s - for product problems only (if known) #2 yes no gogan 10. Concomitant modical products and there within Oxide 60m is broken Losie 40m IV 5000 00 Suspect medical device on 400cc 61000g e) a few house after tradifier, 2. Type of device Transferred back to Icer, GI consult obtained - upon 60 6 level thought to be secondary to MSAID + ASA US 3. Manufacturer name & address

strong relies. Had no finither 5 lealing of the stanting spritable + succeptante 5/20/01 Het \$9.3 5/24/01 Het 42,4 5/25/01 Ht 42.2 5/24/01 Ht422 H+ 43,0 ant history, including precising medical conditions (e.g., allergies

JUN - 7 2001



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

E. Initial reporter calth professional? 🔀 yes 🔲 no Alma Brockition

9. Device evaliable for evaluation?

□ no

☐ yes

ILIN_0 8 200

10. Concomitant medical products and therapy dates (ptill) traitment seems

-DSS	•
III - C 1001	
4 Initial reporter also	

yes no unk

(Do not send to FDA)

meturned to manufacturer on

Obgratur of device health professions! lay Jser/patient other:

Expiration date

If Implanted, give dat .

if explanted, give date



Patient information Patient identifier 2. Age at time of event:

or VOLUNTARY reporting

Form Appr	oved: OMB No. 0910-0291 Expires:12/31/ See OMB statement on reven
FDA Use Only	
Triage unit sequence #	145632

health professionals of adverse events and product problems Page ___ of ___CDET

A. Patient in			C. Suspect medic		
Patient identifier	2. Age at time of event: 7 \(\)	3. Sex 4. Weight	Name (give labeled strengt	•	
2964	or ———	female lbs	#1 WARFARI		
	Date of birth:	[Artie	#2 ASELD.	1 PIR DOLLAR	tes (if unknown, give duration)
In confidence			2. Dose, frequency & route u	used 3. Therapy da	tes (if unknown, give duration)
	event or product proble		#1 5ma QD & 7,57	from/to (or best	estimate;
1. Adverse even	ited to adverse event	(e.g., defects/malfunctions)	7		/
(check all that appl			#2 325m. QD / 20m		
death		al anomaly	4. Diagnosis for use (indicati	on)	5/ Event abated after use stopped or dose reduced
life-threatening		intervention to prevent nt impairment/damage	#1 A-F.B	-	
	- initial or prolonged other:	n inpairiteiradamage	#2 PROMYKAXIS / AT	CYNRIT W	#1
			6. Lot # (if known)	7. Exp. date (if known)	#2 Tyes no doesn'i
3. Date of 4	4. Date of this report		#1	#1	8. Event reappeared after
(rno/day/yr)	(mordayryr)		#2	#2	reintroduction
5. Describe event or	problem			<u> L</u>	#1yes no deeSn1
115			9. NDC # (for product problem	s only)	#2 yes no doesn'i
POLE L.	ANOTIC STOOL	٠٠٠.	10. Concomitant medical pro	oducts and therapy dates (s	
>	Zweees		ATEMOLOL-	,,	- Total Control Control
	2 20 8 2 2 3		NIFECIPINE		
			,		
			TENAZOSIN		
			D. Suspect medic	cal device	
			1. Brand name		
			2. Type of device		
			3. Manufacturer name & add	ress	4. Operator of device
					health professional
					lay user/patient
					other:
			6.		5. Expiration date
			model #		i i i i i i i i i i i i i i i i i i i
6. Relevant tests/lab	poratory data, including dates			ECEIVED	7. If implanted, give date
		D00	catalog #I_	-OLIVEL	mo/day/yrl
/~/	R = 3.5	DSS	serial #	HIN A 8 2004	
	-		fot #	0011 0 0 2001	8. If explanted, give date (mo/day/yr)
		JUN 1 1 2001	other # MED	WATCH CTI	
			9. Device available for evalua	ation? (Do not sen	d to FD6)
			yes no	returned to manufac	• •
			10. Concomitant medical pro	ducts and therapy dates (e	imo/day/yr)
				(a	Addoct Galment of Everty
	story, including preexisting medical				
race, pregnancy, s	moking and alcohol use, hepatic/renal	dystunction, etc.)			
		Į.		onfidentiality section	on back)
			1. Name, address & phone i	I OKS VA MEDICAL	CENTED .
			510 EAST STO		CENTER #
				OUISIANA 71101	-4295
			(318)-424-600		
) m	(56)			Occupation	4. Also reported to
CTU 14				PPA_	manufactu er
Ma Ma	ail to: MEDWATCH 5600 Fishers Lane	OF FAX to: 1-800-FDA-0178	yes no		user facility
	Rockville, MD 20852-9787		5. If you do NOT want your in the manufacturer, place a		distributor
FDA Form 3500 (6/93)	Submission of a report does i	not constitute an admissio	L		





Form Approve	60 by FUA: 05/22/95
Mfr report #	601-24477
UF/Dist report #	
	EDA Hea Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page $\frac{1}{2}$ of $\frac{2}{2}$

Patient information		C. Suspect medicati	ion(s)
Patient Identifier 2. Age at time	3. Sex 4.Weight	1. Name (give labeled strength & mfr/	/labeler, if known)
of event:	female lbs	#1 LOVENOX 30 MG/0.3ML\30\AV	/ENTIS PHARMA
or			
In Confidence of Birth:	✓ male or kgs	#2 ASPIRIN	
B. Adverse event or prod	luct problem	2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration)
	duct problem (e.g. defects/malfunctions)	#1 1 MG/KG\Q12H	from/to (or best estimate)
2. Outcomes attributed to adverse event	duct problem (e.g. derects/maint/volions)		#1
(check all that apply)	disability	#2	#2
death	congenital anomaly	4. Diagnosis for use (indication)	5. Event abated after use
Fi	required intervention to prevent	#1 NOT SPECIFIED	stopped or dose reduced
life-threatening	permanent impairment/damage		#1 J yes no doesn't
hospitalization – initial or prolonge	d other:	#2 UNKNOWN	apply doesn't
<u> </u>		6. Lot # (if known) 7. Exp.	date (if known)
event	4. Date of this report AUG- 8-2000	#1 #1	8. Event reappeared after reintroduction
(mo/day/yr)	(mo/day/yr)	#2 #2	C C C doorn't
5. Describe event or problem		9.NDC # for product problems only	The state of the s
A PHARMACIST REPORTS THAT	A MALE PATIENT		#2 yes no doesn't
EXPERIENCED PETECHIAE IN	THE FACE, LEFT EYE		
SUBCONJUNCTIVAL HEMORRHAG		10. Concomitant medical products	and therapy dates (exclude treatment of event)
GASTROINTESTINAL (GI) BLE			
RECEIVED ENOXAPARIN (1 MG			
OF 10 DOSES. CONCOMITANT			
ASPIRIN AND PLAVIX, BOTH CONTRIBUTED TO THE BLEEDI		G. All manufacturers	s
ASPIRIN, AND PLAVIX WERE	•	1. Contact office - name/address (&	
AN OPHTHALMOLOGY AND GI C		, , , , , , , , , , , , , , , , , , , ,	(610) 454–8143
RECOVERED AND ENOXAPARIN		AVENTIS PHARMACEUTICAL	PRODUCTS Inc.
HIS PAST MEDICAL HISTORY			3. Report source (check all that apply)
END-STAGE RENAL FAILURE,		500 Arcola Road	foreign
RECEIVING DIALYSIS.		P.O. Box 1200	1
			study
(THE MANUFACTURER OF PLAV	IX WILL BE NOTIFIED OF	Collegeville, PA 19426-0	107 literature
THIS EVENT)			consumer
		 	
(SEE US01-24479 AND US01-	24480, SAME REPORTER)	4.Date received by manufacturer 5.	
		APR-10-00	A)NDA # 20-164 user facility
		8. If IND, protocol #	IND# company
		[[PLA# representative
6 Pelevent tests/ishornton, data institute of	stoc	7. Type of report	pre-1938 yes distributor
6. Relevant tests/laboratory data, including da	8182	7. Type of report (check all that apply)	orc H H other:
		5-day 15-day	product yes
			Adverse event term(s)
		TU-day J periodic	PETECHIAE, FACE
			LEFT EYE SUBCONJUCTIVAL HEMORRHAGE GASTROINTESTINAL BLEED
		9. Mfr. report number	
		US01-24477	
		337	
	-	E. Initial reporter	
7. Other relevant history, including preexisti	ing medical conditions (e.g., allergies,	1. Name, address & phone #	
race, pregnancy, smoking and alcohol use, h		HOSPITAL	/001
END-STAGE RENAL FAILURE W	TITH DIALYSIS.	STREET	Jun 1 2 4001
•		UNITED STATES	
	İ	2. Health professional? 3. Occ	supation 4. Initial reporter also
			MACIST Sent report to FDA
	,	yes no	yes no Juni:



AVENTIS PHARMACEUTICAL PRODUCTS Inc. 500 Arcola Road P.O. Box 1200 Collegeville, PA 19426-0107

2. Dose, frequency & rou #3	ite used	3. Therap from/to #3	py dates (if unknown, give duration) (or best estimate)
#4		#4	
4. Diagnosis for use (ind #3 UNKNOWN	ication)		5. Event abated after use stopped or dose reduced doesn't apply #4 yes no doesn't doesn't
6. Lot # (if known)	7. Exp. dete (if known) #3		8. Event reappeared after reinfroduction
34	#4		w3 ves no doesn't
9.NDC # - for product pro	blems only (if kno	own)	#4 yes no doesn't apply

TUN : 4 LOOL



MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems 13 FL

Form Approved: OMB No. 0510-0251 Express 12/31/ See OMB statement pat rever

11-200 und 145693

A. Patient information	C. Suspect medication(s)
1 Patient identifier 2 Age at time of event: 3. Sex 4 Weight	Name (give labeled strength & mfr/labeler, if known)
S1473 Or Date Date	" ASA Do (don't know sto th)
In confidence of birth:	12 V. SO. 335 m 0 + 1 3 VO 300 5 +
B. Adverse event or product problem	2 Dose, frequency & route used) 3 Therapy dates til unknown, give sufation
Adverse event and/or Product problem (e.g., defects-mail/unctions)	"Sunkasia " all 3 the mis- toold
Outcomes attributed to adverse event	1 230m ortid Dent 121
concentral anomaly	4 Diagnosis for use indication: 5 Event abated after use
death required intervention to prevent life-threatening permanent impairment damane	stopped or dose reduced
rise-threatening permanent impairment/damage Chospitalization - initial or prolonged other	2 YY
	6 Lot # til known 7 Exp. date til known 2 yes no acesn t
Oate of event CS/DC this report 3/30/C/	8. Event reappeared after reintroduction
Describe event or problem	#2 #2 pg Topeson to
Admitted from ER To needs and of coffee.	9 NDC # ifor product problems only) #2 yes no Treesit
Good enesis transled hypotherision. Le	10. Concomitant medical products and therapy dates rexclude 'realment of events
the of melore or diagnoses. The protect was	Les confirme on program MV2 > moted
on ASA. Har of constatis but no PUD	[E 20 395 6 4 4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Hemocraft (t) GI consalt when out	The same to letter.
Weer consing Heart. Suspect Mullary-Was	Menuse Simple KCADUCE is tid
time from visiting - upper endoscopy	D. Suspect medical device
ruled of Mallory- Wess team but evidence	
of hemorrhading. Pemes, swhile in hispital	2. Type of device
on mo white evidence it blending in	Manufacturer name & address 4 Operator of device
NG tubing or fluid drawn translate.	health professional
	lay user:oatien!
Pt remared hamodynamically stable while] other
in hospital.	
	6. Expiration date
Determined transfer to the control of the control o	model: HECEIVED
HCT HqB INIZ 106 1.14	catalog #7. If implanted, give date
	senal # JUN 2 0 2001
11.1 34.5 Albania (015 3.1) 10.8 33.4	lot # If explanted, give date
10.5 >5.4 11.1 34.4	other #
	9. Device available for evaluation? (Do not send to FDA) yes ro returned to manufacturer on
1 12.4 35 6	10. Concomitant medical products and therapy dates rescribe trealment of events
Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic renal dysfunction, etc.)	
ATD BPH & writery retention	E. Reporter (see confidentiality section on back)
CAD TVO	Name, address & phone a
demedia dul to EACH diserticulosis	
Alzeihmer's UTI's	
arthritis anima	
multiple CVA's	Health professional? [3. Occupation 4 Also reported to
Mail to: MEDWATCH or FAX to:	2. Health professional 7 3. Occupation 4 Also reported to manufacturer
5600 Fishers Lane 1-800-FDA-0178	5. If you do NOT want your identity disclosed to
Rockville, MD 20852-9787	1 the second colors of the second sec

FOA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.



3742362-4-00-01	C	ע			
meDWatch ()	DEI ES	Approved by FDA on 10/20/93			
THE PDA MEDICAL PRODUCTS REPORTING PROGRAM	S	Tria	Triage unit sequence # 145593		
	Page 1 of				
A. Patient Information	į	C. Suspect Medication(s)			
1. Patient Indentifier 2. DOB:		1. Name #1 : ASPIRIN			
B. Adverse Event or Product Problem	=======================================				
1. [X]Adverse Event []Product problem	2	2. Dose,frequency & route used - #1:		3. Therapy dates	
2. Outcomes attributed to adverse event [
initial or prolonged prevent impairme	ent/damage	#1:		stopped or dose reduced? #1: [N/A]	
3. Date of event 4. Date of this 08/11/00 05/02/01	}-				
5. Describe event or problem GI bleed	1	#1:	 #1:	e 8. Event reappeared after reintroduction #1: []	
		9. (Not applicable to adverse drug event reports)			
FECEIVED JUN 1 9 2001 MEDWATCH-CTU 7. Other relevant History, including preexisting medical conditions		10. Concomitant medical products/therapy dates(exclude treatment			
		Note: Please use the actual MedWatch form if the event involves a suspected device as well as a suspect drug			
		E. Reporter			
	i 3	BZOO VINE SI CINCINNATI C	-		
Mail to: MedWatch or FAX to: 5600 Fishers Lane 1-800-FDA-0178 Rockville, MD 20852-9787		2. Health professional? 3. Occupation 4. Reported to Mfr. [YES] , PHARMACY RESID [NO]			
	 5 		nt your identit	y disclosed to the Manufacturer	
FDA Form 3500	==	***********			

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTV145593

State of the processor State of the proces	Individual Safety Report *3742368-5-00-01*	4111
Application Application	A. Palientinformal	events and product problems
2. Optionnes attributed to adverse several growing and product and several several control of the several several growing and several several growing and product and several growing and product and several growing and product and several growing and product and several growing and product and	I 88 of event: 5 3 Sex of teme of event: 5 3 Sex of tempe of event: 5 3 Sex of tempe of birth: 5 3 Sex of tempe of birth: 5 3 Sex of tempe of birth: 5 3 Sex of tempe of birth: 5 3 Sex of tempe of birth: 5 3 Sex of tempe of birth: 5 3 Sex of tempe of birth: 5 3 Sex of tempe of tempe of birth: 5 3 Sex of tempe	or warfann 2.5 mg pe gel.
Strong above and proposed Come Company Come Company Come C	2. Outcomes attributed to adverse event (check at that apply) disability disabi	## 2 15mg PO QD 1 1 W 4 YEAVS 4 Diagnosis for use impositions
bioacd on 12/29 - coumading Ass Stopped MR 657 and Hg 5.5 at that time. Pt then prometed to have all large emess will large and small clots and passed thad per receive. Will large and small clots and passed thad per receive. Will large and small clots and passed thad per receive meaning to insert NoF pt room-thed large and of done blood the wink thing to insert NoF pt room-thed large and of done blood the stansfered to Lou and 2 more units of FFP/ PRBC given and passed on IV H. blockers on 12/20 Eap given and passed on IV H. blockers on 12/20 Eap given and passed on IV H. blockers on 12/20 Eap given and passed on IV H. blockers on 12/20 Eap given and passed on IV H. blockers on 12/20 Eap given and passed on IV H. blockers on 12/20 Eap given and passed on IV H. blockers on 12/20 Eap given and passed on IV H. blockers on 12/20 Eap given and passed on IV H. blockers on 12/20 Eap given and passed on IV H. blockers on 12/20 Eap given and passed on IV H. blockers on 12/20 Eap given and passed on IV H. blockers on 12/20 Eap given and passed of IV H. blockers on 12/20 Eap given and passed of IV H. blockers on 12/20 Eap given and passed on IV H. blockers on 12/20 Eap given and passed on IV H. blockers on 12/20 Eap given and passed on IV H. blockers on 12/20 Eap given and passed on IV H. blockers on 12/20 Eap given and passed on IV H. blockers on 12/20 Eap given and passed on IV H. blockers on 12/20 Eap given and passed on IV H. blockers on 12/20 Eap given and passed on IV H. blockers on 12/20 Eap given and passed on 12/20 Eap given and passed on 12/20 Eap given and passed on IV H. blockers on 12/20 Eap given and passed on 12/20 Eap given and passed on 12/20 Eap given and passed on 12/20 Eap given and passed on 12/20 Eap given and passed on 12/20 Eap given and passed on 12/20 Eap given and passed on 12/20 Eap given and passed on 12/20 Eap given and passed on 12/20 Eap given and passed on 12/20 Eap given and passed on 12/20 Eap given and passed on 12/20 Eap given and passed on 12/20 Eap given and passed on 12/20 Eap give	3. Date of event of problem 12/19/00 4. Date of this report 01/30/0	#2 Sevent abaled after use stopped or dose reduced Stopped or dos
trying to insert Not pt romitted large and of dark blood live NS, 2u pep, 2u probe to 1cu and 2 mere units of FEP/PRBC. given and placed on IV H. blockers On 12/20 EGD revealed linear esophageal viceration and evidence of search bloed. Langupraviol (but and 2 mere units of FEP/PRBC revealed linear esophageal viceration and evidence of search bloed. Langupraviol (but and provious). EED that revealed pub on 12/26 pt transierred back to noising home. Why 9.1 folk he was progressively improving. Warfarin bus not resumed and pt switched to Hepann sobous of the was progressively improving. Bate Hay Hat Insc. 12/19 5.5 16.1 6.67 12/20 8.4 23.7 1.10 12/21 9.3 27 0.88 12/21 9.3 27 0.88 12/21 9.3 27 0.88 12/21 9.3 27 0.88 12/21 9.3 27 0.88 12/21 9.3 27 0.88 12/21 9.3 27 0.88 12/22 9.3 27 0.88 12/23 9.3 27 0.88 12/24 9.3 27 0.88 12/25 16.1 0.9 13/26 6.4 23.7 1.10 12/26 6.7 1.10 12/27 19.3 27 0.88 12/28 10.9 13/26 6.9 1.0 1.0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	black on 12/29 - coumadin ? ASA Stopped. MR 6 and Hg 5.5 at that time. Pt then practiced to he large emesis will arms and could talk	9. NDC # (for product problems only) 10. Concernitation and in the second seco
PECAT Bleed. Langsprazole 60ng pobid mas started and articoags held. Pt had previous. Eff hat revealed and articoags held. Pt had previous. Eff hat revealed piD on 12/9. If had previous. Eff hat revealed on 12/12. If had previous. Eff had previous. Eff had revealed by the provious of t	trying to insert NGT pt romitted large and there will VF NS, 24 FFP, 24 FRBC + SO VITK was giren. We diven and sixed and 2 more units of FFP/PRE	bload las D. Suspect medical days
W Hg 9.1 \$ bit he was progressively improving. Was not resumed and pt switched to 6. Retevant restandabotary data, recycling outes 12/14 5.5 16.1 6.67 12/14 9.3 2.7 0.86 12/15 16.9 4 23.7 1.10 12/21 9.3 2.7 0.86 2/15 16.9 4 23.7 1.00 12/21 9.3 2.7 0.86 2/15 16.9 4 23.7 1.10 12/21 9.3 2.7 0.86 2/15 16.9 4 23.7 1.10 12/21 9.3 2.7 0.86 2/15 16.9 4 23.7 1.10 12/21 9.3 2.7 0.86 2/15 16.9 4 23.7 1.10 12/21 9.3 2.7 0.86 2/15 16.9 4 23.7 1.10 12/21 9.3 2.7 0.86 2/15 16.9 4 23.7 1.10 12/21 9.3 2.7 0.86 2/15 16.9 4 23.7 1.10 12/21 9.3 2.7 0.86 2/15 16.9 4 23.7 1.10 12/21 9.3 2.7 0.86 2/15 16.9 4 23.7 1.10 12/21 9.3 2.7 0.86 2/15 16.9 4 23.7 1.10 12/21 9.3 2.7 0.86 3. Device available for evaluation? (Do not send to FDA) 12/25 16.9 10.9 10.0 10.0 10.0 10.0 10.0 10.0 10	recent bleed. Lansoprazole 60mg poblid mas start pub on 12/9. 24 PRBC given: INR \$ 1.16 (12/20	2. Type of device 3. Manufacturer name & address
17/1 5.5 16.1 6.87	Werfarin was not resumed and pt switched to Heparin 5060U SC BID. 6. Relevant testal aboratory data, society and superior state of the second	11 · JUN 1 9 200
12/21 9.3 27 0.88 9. Device available for evaluation? (Do not send to FDA) 12 15 10.9 9.5 3.5 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy dates (exclude treatment of event) 10. Concomitant medical products and therapy	12/19 5.5 16.1 6.87 12/19 9.44	7. if implanted, give date security:
- HTN - Depression 1/0 Pub - DM - Scievre d/0 - CAD - CAD North Chicago VA Medical Center 3001 Green Bay Road North Chicago, Illinois 60064 Mail to: Autin Warth or FAX to: S600 Fishers Lane Rockville, MD 20852-9787 1-800-FDA-0178 Also reported to Phar macicity Also reported to Phar mac	12/21 9.3 £7 0.88 12/15 10.9	9. Device available for evaluation? (Do not send to FDA)
Mail to: NEDWATCH or FAX to: Secon Fishers Lane 1-800-FDA-0178 North Chicago, Illimois 60064 Whealth professional? 3 Occupation Also reported to Phar macist Also reported to Phar macist	- HTN - Depression h/o PUD - DM - Seizure d/o - CAD	E. Reporter (see confidentiality section on back) —
DA Form 3500 (5.03) Manufacturer S If you do NOT was to	Mail to: AUFDWATCH or FAX to:	North Chicago, Illinois 60064 Health professional? 3 Occupation yes no Programatics Also reported to
Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event. Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event. Cold 12 Int 1991 Clinical Pharmacy 531	Submission of a report does not constitute an admission	that medical personnel or the product caused or contributed to the event.



71	ADR C	ONTINUA	TION RE	PORTIN	C SHEE	117370
PATIENT:	1188				OSITE	I
PAST						
MEDICAL	DM HTI					
HISTORY		Depression				
MSTORT	Seizure	djó.				
MEDICATION						
UPON TON	8					
ADMISSION	_					
	20					
PHYSICAL	BP	TEMP (OTHER _			
EXAM	DIROR		T. INFO			
SERVILLE	PULSE	RESP				
EKG						
ABS				· · · · · · · · · · · · · · · · · · ·	-	
						7
115 INR 2.3	14/19 (1:46)	12/91	1955	**		
PT 27.5.	INR 6.87	<u> </u>	lct		4	
19 INR 9.4	PT 47.2			·		
1:16) PTT 47.2	PT 73,q	1eto				
12T 99	INR 1 1.6.		4			
11 99						
	nussinghome	,				
QUENCE	12/19/4:42	A - OSach	6-10 as	1101	0	
•	12/19/4:43	dans	voe occu	C+ CCoo	\	
ENTS	11:43 lab	- curul -	critical.	lab rep	roct	JUN S 0 Z00
	hold warfar	ha				
	18:06 par	ex emes	is wolla.	Ism de	to	1110 DA D
5570	m rise		, , , , , , , , , , , , , , , , , , , ,			MMM (IVANA)

145570

PAGE	2 OF ADR CONTINUATION REPORTING SHEET
PATIENT:	√ ≩
SEQUENCE (12/1	9) 17:45 vomit legant de blood when in NG tube.
OF	IVF NS 24 FFP ! PRBC SC VITK
EVENTS	EGID candidal esophagistis and DU.
19:41 4u	FFP 44 PRBC total.
	ared on H2 blockers.
	re more hematemesis? one melena.
(32	l. FFP/PRBC.)
	· mid cooph linear ulrecation i exudation of evidence
12 pm of recent	bleed, no active bleeking Atpresent time
losse gro	unds in stronact. 7AM I more inematinesis
1 Lans	opravole to 60mg pobid. monisaid no curticuage.
14:24 mile -	brige wine IVF -> DSI/2NS VITK SQ.
JU ₽	PP PRBC large and blackish stool
	e stage and totallish stort
12/21) - 14:42	I tarry mod loose stool iVF -DS N D/e.
18:54	no vont poliqueds. ting clots in wring L hem
20:20.	pul uni
	amber coloced wine
((:)	ont cansop 60mg BID for 8 wb then I doke to 30mg/ki
12:42 M	active belording.
arted on (ansop	30 mg bid on 12/9/00
2/23) 1:30 am	uber wrine
9,10	the state of the s
21:20 a	londy yellow. (12/26) transferred faith
1	
	will franker on 12/26. stable
45570	1911 Stible
	12/29 no c/o N/V NO GI bleed
	noted.



| MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN | MIN

For VOLUNTARY reporting by health professionals of adverse events and product problems Triage Unit Sequence # 145716

....

Page 1 of 1

A. Patient Information	C. Suspect Medication(s)
1. Patient Identifer 2. Age at time of event: 3. Scx 4. Weight	I. Name (give labeled strength mfr/labeler, if known)
Or Date of birth: M 1hs	#1 geody's pewder
(In confidence)	#2
B. Adverse Event or Product Problem	2. Dose, frequency, route used 3. Therapy Dates (from/to)
1. Adverse Event and/or Product Problem	#1 5 x a day PO
2. Outcomes attributed to adverse event Disability	4. Diagnosis for use (indication) 5. Event abated after use
Life-threatening Congenital anomaly	#1 stopped or dose reduced
Required intervention to	#2 #1 Yes
Hospitalization - prolonged impairment/damage	6 Lat # (Sharms) 7 Eng data
	6. Lot # (if known) 7. Exp. date 8. Event reappeared after reintroduction
3. Date of event 4. Date of this report (moldaylar) 5/3/01 (moldaylar) 5/1/01	#2 #2 #1 Unknown
(mo/day/yr) 5/3/01 (mo/day/yr)	9. NDC # (for product problems only) #2
5. Describe event or problem	
A pharmacist reported that a patient began taking Goody's Powders	10. Concomitant medical products
(aspirin) on an unspecified date for an unspecified indication. On 3-May-01 the patient experienced GASTROINTESTINAL BLEEDING.	
The reaction was treated by discontinuation of the medication,	DSS.
administration of blood products and ADMISSION TO THE HOSPITAL. The reaction was reported to have resolved.	300
HOSPITAL. The reaction was reported to have resolved.	JUN 2 0 200
!	0 200
DECENIED.	D. Suspect Medical Device
RECEIVED	****
JUN 2 0 2001	These fields not used for electronic 3500 reporting at
MEDWATCH CTU	I-AI ADD E
MEDWATOTIO	Internal ADR Event Coding
	Reaction 1: bleeding
	Reaction 2: hemeternsis, melena
6. Relevant tests/laboratory data, including dates	Reaction 3:
Serum Creatinine:	Reaction 4:
hematocrit 19 %	Reaction 5:
	E. Reporter (see confidentiality section on back
	1 1
!	1. Name, address and phone # ADR Program Coordinator / Drug Information Service
7. Other relevant history, including preexisting medical conditions	Department of Pharmacy and Drug Information
Allerging NKA	Box
JUN 19 2001	The second secon
, 3 2001	
	2. Health Professional 3. Occupation 4. Also reported to
CTV145716 Mail to: MEDWATCH or FAX to: S600 Fishers Lane	Yes No Pharmacist manufacturer
Mail to: MEDWATCH or FAX to:	5. If you do NOT want your identity disclosed to the manufacturer, place an
FDA 5600 Fishers Lanc 1-800-FDA-0178 Rockville MD 20852	"X" in this box.



MedWatch

The FDA Medical Products Reporting Program

Health Division
For use by user-facilities,
distributors and manufacturers for
MANDATORY reporting

Page 1

Merck Facsimile of FDA Form 350CA Approved by FDA (10/21/93)

Mfr report #	WAES 01021272
UF/Dist report #	
	FDA Use Gniy

A. Patient information		C. Suspect					
Patient identifier Age at time of event: Sex	4. Weight	Name (give labeled stre Name (give labeled stre Name (give labeled stre	-		n		
or 80 years Fee	male 154 lbs		TAT 0.4 IIICIC	Jgrisky i i ii			
Date of X Ma		#2 heparin Unk	(Continued	l on Additio	nal Page)	1	į
	blom	2. Dose, frequency & route				i (if unknown, giv	e guration
B. Adverse event or product pro	em (e.g., defects/marfunctions)	#1 Unk/Unk/IV		#1 C	02/??/01 -	02/??/01	
Outcomes attributed to adverse event (check all that apply)	ity	#2 Unk/Unk/IV		# 2 C	02/7?/01 -	02/??/01	
geath Conger	rital anomaly	Diagnosis for use (indicate)	•	1	5.Event abale reduced.	ed after use slopp	ped or dose
(mo/day/yr) require	ed intervention to prevent ment impairment/damage	#1 non-Q-wave m	yocardiai inia	rction	yes #1 X	AVA on	unk
	important medical	5. Lot # (if known)	7 Exploate (if	(«nown)	# 2		X
3. Date of event 02/??/01 4. Date of this report (mo/day/yr)	06/13/01	# 2	ļ 		8. Event reap	peared after rein	t-canction
S. Describe event or problem		9. NDC # - for product prob	ems anly (d knor	<u> </u>	yes	™ N/A	unk
Information has been received from a pleoncerning an 80 year old hospitalized:		 	•		*1 🔲		
with hypertension, benign prostatic hype	erplasia, diet	l [nown	1	# 2		X
controlled diabetes, chronic renal insu- coronary artery disease, and a penicill history of lipoma removal, transurethra.	in allergy, and a linesection of the	10 Concomitant medical p ALDOMET (METHY) COLACE		apy dates (exc	duded treatme Unk -Un Unk -Un	ık	
prostate, and smoking (quit 20 years ago on therapy with tirofiban HCl (dose not	reported) for the		(Continued	on Additio	nal Page)		
treatment of non-Q-wave myocardial infa- Concomitant suspect therapy included he		G. All manu	facturer	s			
duration, and indication not reported) (total daily dose, duration, and indicat		1 Contact office - name/ad				2. Phone Numb	ær
reported). Concomitant therapy included	isosorbide	Merck Human	Health Div	vision	1	(610)397-	2416
dinitrate (Isordil), metoprolol tartrate methyldopa (MSD), desipramine, fosinopri		Merck & Co., I		131011	3	Report source	$\overline{}$
clonidine, and docusate sodium (Colace), reported that in February 2001 (exact da	. The physician	P.O. Box 4	116.		1	(check all that a	300ly)
patient presented at the hospital with a	non-Q-wave	West Point, PA	10406 00	004		toreign	
myocardial infarction. Laboratory findir the patient's troponin peaked at 11 and		West Fornt, PA	19486-00	004		sludy	
was 2.1. At approximately 1500, the pati		ATTN: Worldw	ida Produc	st Safatu		literature	ı
/ -				Calety	E .	X health orolession	i
(Continued on Additional Page)		Date received by manufaction (mo/day/yr)	acturer 5 15/01	NDA # 209		orolession user facilit	- 1
6 Relevant tests/laboratory data, including dates Refer to Additional Page			13/01	IND #		company	
Refer to Addictoral Page		6. If IND, protocol #		PLA *	 -	distributor	tive
		7. Type of report		pre-1938	yes	other	
		5-day 15-day		oroduct	yes		
	Ĭ	10-day X periodic		9. Mfr. report r	number		
		X initial Follow-u	p#		WAES 0	1021273	
		8. Adverse event term(s)					
		GASTROINTESTINA HEMORFHAGE; HEM	L BLEEDING ATOMA	G; EPIST.	AXIS; GI	NGIVAL	
							1
7 Other relevant history, including preexisting medical conditions							
(e.g., allergies,race,pregnancy, smoking and alcohol use, hepaticirent	· ·						
MEDICAL HISTORY: lipoma surgery; smoking prostatectomy	; transurethral	E. Initial repo					
CONCURRENT CONDITIONS: arm pain; benign hyperplasia; chronic renal insufficiency	prostatic	Harte, address & priorie *					•
disease; loose stool; penicillin allergy	: diabetes	233 EAST HURON					
mellitus; epigastric pain; hospitalizati	on; hypertension	LAKESIDE VETERA		AL			
	İ	CHICAGO, IL 60611					1
Submission of a report does not constitute a	an admission that	2. Health professional?	3. Оссыраты	n T	4 cotton espec		
DA medical personnel, user facility, distributor, r		X YES NO	M.:	D.	seri report		() unk



Page 2

MFR Report #:

WAES 01021272

(continued)

B. Adverse event or product problem

5. Describe event or problem

on therapy with IV heparin and tirofiban HCl, injection (form), 0.4 microgm/kg/min (total daily dose and duration not reported). Eight hours after starting therapy with tirofiban HCl (at 2000-2100 hrs), the patient had bleeding of the gums and a small lateral tongue hematoma. The patient also had black tarry stools and bright red blood per rectum. Laboratory findings revealed that the patient's hemoglobin had decreased from 13 to 12 to 9. The patient's initial platelet count was approximately 190,000, and a subsequent platelet count was 160,000-170,000. The patient's activated partial thromboplastin time (PTT) was initially 75-77, and a subsequent PTT was 80. Therapy with tirofiban HCl was discontinued. Subsequently the patient recovered in 12 hours. The physician reported that the patient underwent successful cardiac catheterization on 14-FEB-2001 and did not have any problems post-procedure.

Additional information has been received from the physician via medical records. It was reported that the patient's date of birth was 11-FEB-1920 (conflicting from previously reported information). Two days prior to admission, the patient began to develop epigastric pain, 5/10, without radiation. The patient had no shortness of breath or diaphoresis. The pain has remained constant until the day of admission. R6 stated that he felt like he had a flu. In the past three to six months, he had noted sharp shooting pain down the left arm whenever he exerted himself, and these pains disappeared once he rested. He did have a loose, nonbloody bowel movement on the day of admission (13-FEB-2001). Laboratory findings on admission were hemoglobin 13.5, platelets 164, potassium 5.9, creatinine 2.0, creatinine phosphokinase (CPK) 324, CPK-MB 6.8, index 2.1, and a troponin of 19. An electrocardiogram showed sinus bradycardia with a heart rate of 55, left axis deviation, LVH with repolarization abnormalities, peak T waves in v2 and v3. ST depression in v5 and v6, unchanged from old EKG. The patient was started on intravenous heparin as well as tirofiban BCI 0.4 mag per minute per kilogram with holding of metopoolol tartrate (Lopressor) for his bradycardia, and the patient was admitted to the coronary care unit. The patient during the course of his hospitalization had no further episodes of chest or epigastric discomfort. The patient's bradycardia, and the patient was admitted to the coronary care unit. The patient was discontinued because of melanic stool with a drop in hemoglobin at 9.2. It was reported that therapy with aspirin was discontinued due to a gastrointestinal bleed during the course of his hospitalization. The patient was evaluated by Gastroenterology during the course of his hospitalization, who felt that the patient likely had an upper GI source for his associated bleed. It was reported that the patient did have one bout of epistaxis. The patient underwent a cardiac catheterization on 15-FEB-2001, hat showed a e

The physician felt that the patient's gastrointestinal hemorrhage, gingival hemorrhage, and hematoma prolonged hospitalization, were immediately life-threatening and were other medical events.

No additional information is expected.

6. Relevant tests/laboratory data, including dates

DIAGNOSTIC TEST

Tests Date Value Unit Normal Range electrocardiogram 02/13/01

Comment: sinus bradycardia with heart rate of 55, left axis deviation, LVE with repolarization abnor, p eak T

cardiac catheterization 02/15/01

Comment: 3 vessel disease

ultrasound 02/15/01

Comment: showed no pseudoaneurysm, fistula, or hematoma

LABORATORY RESULTS

<u>Tests</u>	<u>Date</u>	<u>Value</u>	Unit Normal Range
APTT	02/??/01	75-77	
APTT	02/??/01	80	
hemoglobin	02/??/01	. 13	
hemoglobin	02/??/01	12	;
hemoglobin	02/??/01	9	
platelet count	02/77/01	190,000	
Comment: approximately			
platelet count	02/??/01	160,000-170,000	
serum Ini	02/?7/01	• • • • • • • • • • • • • • • • • • • •	
serum creatinine	65.33 01	2.1	
nemoclobin	€9713+9 1	13.5	
hemoglobin	03/77/51	9.3	

(continued)



	e 3	мгн нероп #:	WAES 010212/2	(continued)
platelet count	02/13/01	164		
serum TnI	02/13/01	19		
serum creatine kinase	02/13/01	324		
serum creatine kinase isoenzyme MB	02/13/01	€.8		
serum creatinine	02/13/01	2.0		
serum potassium	02/13/01	5.9		
left ventricular ejection fraction	02/15/01	45 9	}	

MED Danage

WATE 01001073

C. Suspect medication(s)

- 1. Name (Given labeled strength & mfr/labeler, if known)
 - #3 aspirin Unk
- 2. Dose, frequency & route used
 - #3 Unk/Unk/Unk
- 3. Therapy dates (from/to) (if unknown, give duration)
 - #3 Unk 02/??/01
- 4. Diagnosis for use (indication)
 - #3 Unknown
- 5. Event abated after use stopped or dose reduced

YES NO N/A

#3

6. Lot # (if known)

ڌ#

7. Exp date (if known)

#3

8. Event reappeared after reintroduction

NO

YES

N/A

UNK

#3

x

C. Suspect medication(s)

10. Concomitant medical products and therapy dates (exclude treatment of event)

ISORDIL Unk - Unk

LOPRESSOR Unk - 02/??/01

clonidine

desipramine fosinopril nifedipine

Unk - 02/3
Unk - Unk
Unk - Unk
Unk - Unk
Unk - Unk





For VOLUNTARY reporting by health professionals of adverse events and product problems

Form Approved:	CIVIEI No. 0010-0231 Expired; See ONE statement on	4000
	See OMB statement on	RWA

146254 Triage unit

111 111 1111	*** **** *** **** *	7MI 1111111		Page _	of 1 C	٠ - ١			
	information or 2. Age at time			4 14 1 2 2	C. Suspect n				
1, Patient Identifi	of event: unki	nown	3, Sex	4. Weight	1. Name (give labeled	ទៅមេកផ្លាក់ ទី កៅមើន	beler, if known)		
	Deta unkr	nown	male	o r	#2			· ·	
in contidence	e event or prod	uct problem		kgs	2. Dose, frequency &	route used	3. Therapy di	ates (if unknown, give d	(urstion)
1. Advetse		roduct problem (maifunations)	#1 325 mg po qo		fromto (or bed	esirrate)	5. 5(15)(1)
2. Outcomes attr	treve expevbs of berudi		J.g., 04100G	maidire doisy			l 		
(chock all that a	abby)	disability	a comely		#2 4. Diagnosis for use	Indication)	#2	E 64	
death	(mo/dayiyr)		tervention to	ргачепт	#1 unknown	o.casar,		5. Event abated after stopped or dose	
life-threate	ring tion – initial or prolonged	permanent other:	impaiment/	damage	#2			#1yesno _	□ doesn
	hau - www a baarded				5. Lot # (If known)	7 Evn	date (ifknown)	#2 yes no	
3. Date of event Apr-	02-01	4. Date of this report	Apr-29-01	l	#1	#1	COLD (I. A.IOMI)	6. Event reappeared	
5. Describe ever				•	#2	#2		#1 vek no	
	ient with a history of aspirin 4 years ago,				9. NDC # (for product p	roblems only)		yes no	apply doesn'
to 4 days ago	. She was admitted	into the hosp	ital on Ar	or-02-01	10. Concomitant med	- -		#2 yes no	doesni
of "coffee-gn no alcohol or emergency de lavage. Aspir Zantac 50 mg	esis. The night she vound' emesis. Prior mon-steroldal anti-tepartment she had a fin therapy was disc g intravenous every and red blood cells are	to hospitaliza inflammatory nasogastric t ontinued. She 8 hours, was	ation the parties of the control of	patient had In the d for ted with d with 2	D. Suspect m	edical dev	vice		
3					2. Type of device				
PLEASE TYPE OR USE on the control of				-	3. Manufecturer name 6. model #			4. Operator of det health profe lay user/pat other: 5. Expiration date (nodes/yr)	essional tient
6. Relevant tests/ unknown	laboratory data, including	dates			catalog #			7. If Implanted, gi	ive date
dikilowii	RE	ECEIV	ED		serial #			— (1TV034/5Y)	
	1	lin o o o	004		lot#			B. If explanted, gi	vo dete
	. J	UN 2 8 20	וטע		other#				
	MFD)	WATCH	CTII		9. Device available for		(Do not sen	1 1. 36.7	
			010			<u> </u>	umed to manufac	(morressor)	ī
					10. Concomitant medic	sas brooncra auc	neusby dates (e	inchile negarati 500	(作)
7. Other relevant race, pregnancy	history, including presxi , smoking and alcohol use	sting medical cor •. hepatic/renal dys	nditions (e.g sfunction, etc	allergies,)					
	isease and gastritis				E. Reporter (s	aa aastidust	1.04		
					1. Name & address		one#	n on pack)	
						Deue Contes			
		JUN	2 8 20	01		Drug Center STE			L
					2. Health professional?	1 .		4. Also reported to	
	Mail to: MEDWATCH 5600 Fishers		FAX to:	A 0479	yes no	pharmacist		manufacturer	
		20852-9787	1-800-FD	M-01/8	If you do NOT want the manufacturer, p	your identity dis	closed to	usor facility distributor	İ
Fb= Form 3600 1/96)	Submission of a	report does not	t constitute	an admissio	on that medical persent				

Jul-03-01 07:45am From-BT PHARMACY OFFICE Individual Safety Report ven	ts and pr	oduct problems	T-13) P.004	/020 F-390
	Page	_ of	P = 1	146489
3751168-1-00-01		C. Suspect medic	cation(s)	
of ent	Veight	1. Name (give labeled strong	•	
6738 or	ar ibs	*1 aspir,		
in confidence of birth:	kgs	2. Dose, frequency & route		tes (if unknown, give duration)
B. Adverse event or product problem Adverse event and/or Product problem (e.g., defects/malfun	nctions)	#1 325mg Pa	QI) Intrinuite (or bosi	e: amaso)
2. Outcomes attributed to adverse event		12 Drn Stomas	h Da #2	
[check all that apply) [check all that apply) [check all that apply)		4. Diagnosis for use (indicati	ion)	 Event shaled after use atopped or dose reduced
(modby/m) required intervention to prever permanent impairment/damag		" CVA		#1 yes no doesn
nospitalization - initial or prolonged other:	-	#2 B. Lot # (if known)	7. Exp. date (if known)	#2 yes no doesn
3. Date of this report 5/11/01		#1	#1	Event reappeared after reintroduction
event O I'll I'll I'll I'll O O O O O O O		#2	#2	#1yes nodoesn
At taking daily aspirin plus		9. NDC # (for product problem	s only) —	#2 yes no best
		10. Concomitant medical pro	oducts and therapy dates (e	
alba settyer for 1-2 weeks p	MOR			
to admission for alidonim				
Presents to ECS with C	101	D. Comment modifie	ol douiso	
·	1-11	D. Suspect medic	ar device	
descuess henatemeses and		2. Type of device		
melena x 3 days. NGL O. A	+	3. Manufacturer name & addi	ress	4. Operator of device
"adutted IW, EED: large				health professional
-				lay user/patient other:
ulcer, gives 2 units PRBCS		·		
lanseprozes and aspirin	•	6. DL	CENTER.	5. Expiration date
Change to desideasel.		model#	CEIVED	
. Relevant tests/laboratory dats, including dates		catalog #	ut 0 3 2001	7. If implanted, give date (monsyly)
Het 37 -> 27	,	serial #NACTV	MATCH CTI	DSS
TILL ST 7 ST	1 1	lot # VIEU	WATCHOLL	in planted, give date
	1 1	other # 9 Device available for evalua	tion? (Do not send	0 3 2001
		yes no	returned to manufact	· ·
		10. Concomitant medical pro-	ducts and therapy dates (ex	
Other relevant history, including preexisting medical conditions (e.g., aller	gies,	Cl.		<u> </u>
race, pregnancy, smolding and sloohol use, hepatic/renal dysfunction, etc.)		E. Reporter (se_ co	entidentiality section	on back)
HTW. CVA MITTY 14				
JUL 0 3 2001		Many land 14 fled	Avermy, 1	Ma rucy (1/4)
2 0 3 201/1		Mary line 64 ble	it Courses	k" 1 ¹ 12
A Lille Land			Occupation	ALD 2/201
Aluere Probable	<u>~</u> .	Cit is to a standard and a land	linical	manufacturer
Mail to: MEDWATCH or FAX to: 5600 Fishers Lane 1-800-FDA-017 Rockville, MD 20852-9787	'8	5. If you do NOT want your		user facility distributor
24 Form \$500 (6/93) Submission of a report does not constitute an a	noisaimbe	the manufacturer, place at that medical personnel or		

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ents.	and	product	problems
, C (1173	ST. ICE	product	F

410 605 7852	T-131	P.003/020	F-390
problems	110	Hauca &	

FINANCIA IN THE BOTH WAS NOT AND THE BOTH THE STATE OF BUT OF THE STATE OF THE STAT	Page	C. Suspect medic	ration(s)	
3/511/0-X-00-01	Sex 4. Weight	Name (give labeled strength	h & mfr/labeler, if knov/n)	
, "lent identifier 2. Age at time	femalebs	#1 Dapirin		
3617 or 74	or	10 10 0	la	
Date of birth:	male kgs	2. Dose, frequency & route	sed 3. Therapy da	ites (if unknown, give duration)
B. Adverse event or product probler	n	1	#1	c annova)
1. Adverse event and/or Product problem (g., defects/malfunctions)	*1 335mg QE	#2	
2. Outcomes attributed to adverse event (check all that apply)		4. Diagnosis for use (indicate		5. Event abated after use
coudeurs:		*1 CAD	•	stopped or dose reduced
	arvention to provent Impalment/damage			#1 yes no doesn
hospitalization - initial or prolonged other:		#2 6000 6. Lot # (If known)	7. Exp. date (if known)	#2 yes no dossn
3. Date of	-1 /	#1	#1	8. Event reappeared after
event 5/14/01 time report (mordayivi)	5/18/01	#2	#2	reintroduction #1 yes no doesn'
i be event or problem	the state	9. NDC # (for product problem	s only)	
Pt presented to ECS with B	is mound	_	-	#2 yes no doosin'i
c/o digguess dark stocks	and coffee	10. Concomitant medical pro	oducts and therapy dates (excinde (testiment of exect)
0,0	A A			
grand enesis. NG lan	Territor .			
At admitted to two, un	led in for			
	- Lundage 1	D. Suspect medic	al device	
mi EGD: large duoden	as week!	1. Brand name		
times H. Alori D. Pt	received	2. Type of device		
lancopragale 7 un anchi cillinger Clarithronger	+ PRRCS.	3. Manufacturer name & add	ress	4. Operator of device
15 lanoprage 100				health professional
(la othronie				other:
	}			
				5. Expiration date
		6.	FCEIVEL	(molday/yr)
		model #	io 2004	7. If implanted, give date
Relevant tests/taboratory data, including dates		catalog #	<u>.,,,,, 0 3 2001</u>	TICC
Hct 32 → 14-9		serial #	FYNALA TOH CT	B. If explainted, give date
1101	1	lot#VIE	DINTION	- Jul 7 7 3 2001
		other #		101 0 3 200
		9. Device vallable for evalu		
		yes ino	returned to manufa	(weresthat).
		10. Concomitant medical pro	HINE BIT THE BY OUT OF	a female il comment
Other relevant history, including preexisting medical co	onditions (e.g., allergies.	O_{i}		
race, pregnancy, smoking and alcohol use, hepatic/renal d	ystunction, etc.)		- Sidentiality coefic	on backl
MIC. AFI b, HTH, DM, prost	ate CA,	1. Name, address & phone	onfidentiality section	iii dii badii,
semeste PUD				
		Pharmacy (119) Mary ken	e valleath con
		16 N G-566	ace ST Re	017 100 2111
	1 1 0	2. Health professional? 3.	Occupation	4. Also reported to
Deven	probable	Tyes 7 no	lipical	manufacturer
Mail to: MEDWATTH	of FAX to: 1-800-FDA-0178	5 If you do NOT want your	identity disclosed to	user facility distributor
Rockville, MD 20852 9787		the manufacturer, place	an " X " in this box.	,
A Form 3500 (8/93) Submission of different does n	ot constitute an admissio	on that medical personnel o	r the product caused o	e contributed to the event.
- 0 5 2	701			
CTU 1116490				
• • • •				

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T-131 P.013/020 =-390

WA- VULUNIARI reporting realth professionals of adverse vents and product problems

FDa Use Daly	
Triuge unit.	146480



3751179-6-00-01	of	
	C. Suspect medication(s)	-
. Patient information 3, Sex 4. Weight	 Name (give labeled strangth & mfr/labeler, if known) 	
Patient identifier 2. Age at time	#1 Lessi	1 11
3538 or sometimes or		
Date of birth:	#2 Copin, in 2 Dose, frequency & route used 3. Therapy dates (if	Unknown, give duration)
In companies store are duct problem	2 Dose, frequency & foots as trade	
B. Adverse event or product problem Product problem (e.g., delects/mallunctions)		
. I was a supply to the supply	#2 81mg QD + #2 537 - 6	014/01
Outcomes attributed to adverse event disability (check all that apply)	4. Discount (62) use (Indication):	vent abated after use
congenital anomaly	#1 string through in	topped or dose reduced
death	"'	yes no doesn't
hospitalization – initial or prolonged other.	#2 CAD #2[yes ∏no ☐doesn't
	6. Lat # (if known) 7. Exp. date (if known)	vent reappeared after
3. Date of this report the report		sintroduction
(mc/dayAff)	H2 #1	Aaz uo gobzu,i
Describe event or problem	9. NDC # (for product problems only)	
A on hepa and aspirin		yes no coesn't
H on heper was -	10. Concomitant medical products and therapy dates (exclusion	de treatment of event)
for atrial thrombus and		
HOTE attill INFORMATION		
CAD. At developed a GI		
CARD. FI SECOND		
bleed while in Iw. GI	 D. Suspect medical device 	
Bleed while in It. at	1. Brand name	
	2. Type of device	
Consulted, EGO 2 duodenal		4. Operator of device
	3. Manufacturer name & address	health professional
uleers which were injected		lay user/patient
		otner:
with exinephrine, lansopragol		
	DECEMEN	
6 Units PRBCs, hepain, appirin	RECEIVED -	5. Expiration date
	6. model * 0 9 7001	
Dicked.	10 0 3 2001	7. If implented, give date
8. Relevant tests/laboratory data, including cates	catalog #	(merozyy)/()
Het 28 -> 21 MENTING.	serial # MEUVALUTU -	
Het 28 - 31 MADIME.	lot #	 If explanted, give date (molecyle)
PT 61	1017	
JUL 0 3 2001	other# Device available for evaluation? (Do not send to	FDA)
4.3.5001	9. Device available for evaluation? (Do not send to yes no returned to manufa sure	r on
,	10. Concomitant medical products and therapy dates (excit	(AUGUSH3/31)
· · · · · · · · · · · · · · · · · · ·	10. Concomitant medical products and marapy baths (base)	ade tradatione at a first
de la distanción de la		x (537
 Other relevant history, including preexisting medical conditions (e.g., allergies, rece, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) 	Me les Juis	X Chir
PUD DM. CHF. AFIB. HTW. DS	E. Reporter (see confidentiality section of	n back)
NO, DM, CATT, MID, MAN,	1. Name, address & obone	he man live
Producte Cd, CAD, CVA 1111 03	2001 Pharm D /	/V////
proclete CA, CAD, CVA JUL 03		
	10 policies sy solo	-113 Liley
		Alex enpatted to
Deute not lies	2. Health professional? 3. Occupation 4.	Also reported to manufacturer
THE OF EAVIOR	tyes on Pharace	Liser facility
Mail to: MEDWATCH or FAX to: 1-800-FDA-0178	5. If you do NOT want your Identity disclosed to	distributor
Rockville, MD 20852-9787	the manufacturer, place an "X" in this pox.	entributed to the event.

severe Mail to: MEDWATCH

600 Fishers Lane Rockville, MD 20852-9787

probable 1-800-FDA-0178

the manufacturer, place an "X" in this box. Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

12 A Galene Si

Health professionel? 3. Occupation

If you do NOT want your identity disclosed to

Harmaust

price plat 2/161

user lacility

distributor

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1 101		,

ith professionals of adverse

DA Use Only		
Erlaga while requestes a	146082	

THE FDA MEDICAL PRODUCTS AND	C. Suspect medication	(s)	
Patient information 7. Patient identifier 2. Age at time 3. Sex 4. Weight	Name (give tabeled strength & mir/la	abeler, if known)	
of event: 70 female — IDS	HI depirin		
Date I mate	#2		II also a ship duralisa)
of birth:	. Dose, traquency & route used	htsp://p [0* 0021 0518	s (il unknown, give dursiion) mals)
to the description of the second of the seco	#1	#1	
The best of active set in the set	#2	#2	
2. Outcomes attributed to advance of the disability congenital anomaly	f. Diagnosis for use (indication)		Event abased after use stopped or dose reduced
death	* CVA CAD	[yes no doesn't
ite-Inreatening permanent impairment/damage	//2		nz yes no doesn't
HOSPITARIZERS)1 = IIIII.d. Cr processes	Д4	_date (if known)	B. Event reappeared after
3. Date of even 6/33/01 this report 6/35/01			reintroduction
(modelytr) 133 U modelytri	#2 #2		u1 ∐yes ∐no ∐doesn': apply
	9. NDC # (for product problems only)		#2 yes no doesn't
At adm. Hed for hemato chegia.	10. Concomitant medical products a	and therapy dates (e	1
Had EGD / colonoscopy one			
Year ago which showed			
_ 5 1	D. Suspect medical de	evice	
diverticuli. This EGO neg	Suspect medical de Brand name		
Go source of vocas CT bland			
O mage I RRC	2. Type of device		
Angiogram (). Blacking see (3. Manufacturer name & address		4. Operator of device health professional
			lay user/patient
A received 9 units PRBCS			other:
and her cole at ony, rantidine.			
and were to	RECE	IVED	5. Expiration date
	6.	9 2004	
	000	3 2001	7. If implanted, give date
Relevant tests/laboratory data, including dates	catalog #	CH CTII	(mo/saylyr)
Het 35 -> 36.1 MEDNATE	serial #VIVVA	VII VI U	8. If explanted, give date
	for #		
JUL 0 3 2001	other #	In	d in EDA)
3 2001	g. Device available for evaluation?	(Do not sen	turer of
	10. Concomitant medical products		(mand3y/yr)
	10. Colicolingiir inggled, b. 3 and	, , , , , , , , , , , , , , , , , , , ,	4
7. Other relevant history, including preexisting medical conditions (e.g., allergies.			
race, pregnancy, smoking and alcohol use, hepathorenal dystone, our	E. Reporter (see confid	entiality section	n on back)
CHF, CAD, DM. CVA, PVD950	1 Name address & phose #		
1		harm!	1 / KR 266 , (1191
JUI 0 3 2001	J. J. William	Con So	1. 1. (1181
July 2	7 .		west bile f
	2. Health professional? 3. Occu	pation 2 4 C.	4. Also reported to
severe probable	I De Chin	، حمد	manufacturer
Mail to: MEDWATCH OF FAX to: 5800 Fishers Lane 1-800-FDA-0178	5 H you do NOT want your Identif	ry disclosed to	user facility
Rockville, MD 20852-9787	the manufacturer, place an "X	" in this box.	distributor

IA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.



LUNTARY reporting h professionals of adverse

Form Approved: O	AB No. 0910-0291 Exp See OMS stateme	res: 12/31/5
FDA Use Only (MB)	* *	

duct problems		Triage unit	46776
or_ COER	Mn		
C. Suspect medic			
Name (give labeled strengt)			
*1 Indometha	ain_	- \ 	
12 ASA (3	25m	2	
2. Dose, frequency & route to	sed ·	8. Therapy dat from/lo for best e	es (if unknown, give duration)
*1 50mg tid)		*1 1/23/	11-74/02/01
12 5 00 grd		#2 / /	-7 4/02/01
4. Diagnosis for use (indicati	on)		5. Event abated after use stopped or dose reduced
" arthri	+;5		#1 yes no doesn't
#2			#2 yes no doesn't
6. Lot # (if known) #1	7. Exp. da #1	ate (if known)	
		····	Event reappeared after reintroduction
#2	#2		#1 yes no doesn't
9. NDC # (for product problem —	is only) 		#2 yes no doesn't
10. Concomitant medical pr	oducts and	therapy dates (
D. Suspect medi	cal dev	ice	
1. Brand name		<u> </u>	
2. Type of device			
3. Manufacturer name & add	1	 	4. Operator of device
3. Manuactular flatile of act	31 699		health professional
			lay user/patient
			other:
RF(CEIV	/FD	
6.	<u> </u>	رياا	5. Expiration date (morday/yr)
	0 9 2	001	
catalog #	ATOL	LOTIL	7. If implanted, give date (mo/day/yr)
serial # MEUW	ATCF	1010	
lot #			8. If explanted, give date (mo/day/yr)
other # 9. Device available for eval	uation?		nd to FDA)
yes no		turned to manufa	citirer on
10. Concomitant medical p	roducts and	therapy dates	(exclude treatment of event)
The second secon			
E. Reporter (see		tiality section	n on back)
1. Name, address & phon		4 14	
a series de la companya della companya de la compan	្រី «និសីន៍» និសី	WINTER I	BLVD.
MA MAC	TONIO	TX 7828	,
1			
2. Health professional? 3		aim D	4. Also reported to manufacturer
yes no			user facility
If you do NOT want you the manufacturer, place	or IDENITY (,, O7 OPEUIOSA	distributor

-- the madical personnel or the product caused or contributed to the event.

MED		CH		health profes vents and pr
V ILLI	PRODUCTS REPORT	ING PROGRAM		Page
	nformation		- 07	
Patient identifier	2. Age at time	50	3. Sex	4. Weight
1297	of event:		female	or lbs
In confidence	Date of birth:		Male male	kgs
. Adverse	event or produ			
Adverse ever		oduct problem	(e.g., defects/r	nalfunctions)
(check all that app	uted to adverse event bly)	disability		
death	(mo/dey/yr)	i beniupen	al anomaly ntervention to	
life-threatenin		permaner other:	nt impairment/o	lamage ·
	n - initial or prolonged	14. Dete of		
event 4	2/01	this report		
Describe event o	r próblem /	4.2	4. 70	
H C	7 4 M	m 43	70 20	1
	. 10	pain,	som	•
abd	sminar)		, -	
mele	na. we	akne	22-	
,,				ml
anst	ric ulce	es co	usia	
/ · <u>.</u>	trie nlee. L NSAID	ne	. "	
with	K / 3// / 2			
Relevant tests/li	aboratory data, includin	ng dates		
	, , , , , , , , , , , , , , , , , , , ,	-		
Other relevant I	nistory, including pree	xisting medica	conditions (e	r.g., allergies, etc.)
race, pregnancy	, этокинд ано аксоного	oo, iropautitielik	ayaldi cikiri	SS
			1111	0 2001
			., 0 .	

Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787

or FAX to: 1-800-FDA-0178

FDA Use Only (MS)	
Triage unit	1.11.0011



VOLUNTARY reporting ealth professionals of adverse rents and product problems

Triago profi	146884
	14/2004

		C. Suspect medic	cation(s)	
A. Patient information 1. Patient identifier 2. Age at time 3.8	ez 4. Weight	1. Name (give labeled strengt		L. Al
of event: 6/	female 2/5 lbs	" Hepasin		antime!
/28/8/6 Date	or kgs	12 Heparin		- 1
in confidence of birth:		2. Dose, frequency & route to	Sample for burd of	es (if unknown, give duration)
B. Adverse event or product problem	defects/melfunctions)	" 1160 un. 8/h 1	11 3-230	1818-3.24 1115
The second of th	, coresponding	12 1300 Units /2	123.24 11	15-3-35 1800
(check all that apply)	omaly	4. Diagnosis for use (indicat		5. Event abeted after use stopped or dose reduced
death	rention to prevent	" acute so	/	#1 Lyes no desprit
Me-presenting beamsustration	pakmenVdamage	12 acuto An	11	
Phospitalization - initial or prolonged other:		6. Lot # (If known)	7. Exp. date (if known)	#2 Yes no doesn't
3. Date of 3 3.5 - 7.1 4. Date of this report	6-8-01	#1	#1	8. Event respensed after reintroduction
(Microsoft))		#2	#2	#1 Dyes One Desert
Dibant relative	red	9. NDC # (for product problem	ne only)	#2 yes
3 03 which Herapy a	1 other	10. Concomitant medical pr	roducts and therapy dates (s	
Historial for AMI	Chest pain	10. Concomitant medical pr	ondoin min molapy and the	•
Timo pinfusion. A	bent			
transferred AM 3-21-0	1 for			
Dassed brief	+ 1/8/ p/0000	D. Suspect medi	cal device	
per actum & other &	um potoms			
(E anemia) M consu	4 obtained	2. Type of device		
(& anemica) to con-	() and of	3. Manufacturer name & ad	Idress	4. Operator of device
3-49-01 Anomia -Bleed	onax			health professional
control - proceeded up	- carr			other.
		I RE	CEIVED	5. Expiration date
				(ma/day/yr)
		model #	ц 1 о 2001	7. If implanted, give date
5. Relevant teste/laboratory data, including dates	1077 53	catalog #	WATCH CTIL	- (working)
3-35-UI HUT 33 HBB II. I A	27 44	certai # VIEUV	MIONO	_
12-26-01 11(-09 179137.67	, , ,	lot #		5. If explanted, give date (morderin)
3-28-01 HET ON 1589.1	APIT 85	other #		
3 24 -07 110 07 100 11.		9. Device systiable (or eve	lustion? (Do not se	nd to FDA)
		D Yes DOD W	returned to manufer	(mother-br)
		10. Concomitant medical	Products and therapy dates	exclude treatment of event)
7. Other relevant history, including presziating medical co-	aditions (e.g., eliergies,	JUL 1 1 2	USC	,
race, pragnancy, smoking and alcohol use, hepatic/renal dys	sfunction, etc.)			2001
3-23 01 acute AMI w/	V. 46		confidential ty section	on on back)
no prior cond h		1. Name, address & oher		
			The	
3-22 01 polypectorny	<u>'</u>	50		
4.0040	and a de a de			
Hypertensien	-CT) RTCIME	2. Health professional?	3. Occupation	4. Also reported to manufacturer
Mell to: MEDWATCH	CPOW/	Ves no	RPh	user facility
5800 Fishers Lane Rockville, MD 20852-9787	- ANDERICA	 If you do NOT went you the manufacturer, place 	ur identity disclosed to se an "X" in this box.	4 7
	LL-mileute na admicel	on that medical personnel		<u> </u>

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its and product problems

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FDA U-+ Only (MB)				
Tridge unit anguence 9	145884			

Page _ Zo1 _ Z

1	A. Patient information				C. Suspect medic	cation(s)	
ľ	1. Pallent identifier 2. Age at time		, Вех	4. Weight	Name (give labeled streng)	th & minhabeler, if known)	•
1	1281816 of event:	61	iemale [*1 'TNK"		
- 1	Care		Male	or	12 17 19 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	-0.403000-	error aspin
	IU Colmoduco	roduct problem		— kgs	2. Dose, frequency & route i	3. Therapy de	tes (if unknown, give duration)
	B. Adverse event or p	Product problem (e		nathunctions)	11 90m2 IVP OF	6-8 1 1 3-0	3 1808
ŀ	2. Outcomes stiributed to edverse	vent	18., 00,00.0.	, , , , , , , , , , , , , , , , , , , ,	11 90mg IVP 05	31 12 3-29	1-3-30->
	(check all that apply)	disability	nomely		#2.325 ma. po 4. Diagnosis foliase (Indicat		5. Event abuled after use
	death (markey)m)	-	ervention to	prevent	" acute m		stopped or dose reduced
- 1	Me-threatening	permenent	impalment/c				#1 Pres no Proprie
l	hospitalization - initial or profor	nged U other:	.,		#2 6. Lot # (if known)	7. Exp. date (if known)	#2 yes no edicesn't
1	3. Dirto of 3-25-4	4. Date of this report	1-8-	01	#1	#1	8. Event reappeared after
l	(makiny/yr)	(morthgryn)			#2	#2	reintroduction
	5. Describe event or problem				9. NDC # (for product problem	1	#1 yes no Passin't
					- Hoo w (not product product)		#2 yes no pagesn't
Į					10. Concomitant medical pr	oducts and therapy dates (exclude treatment of event)
j					reparin	HISINDA	rio
×					asperen	11pitor	
					heparin asperin TNK afenaclot		
ğ							
교					D. Suspect medic	cal device	
TYPE OR USE BLACK INK							
2					2. Type of device		
					3. Manufacturer name & edd	Irees	4. Operator of device
٦							health professional
13							lay user/patiens
PLEASE							34.2
E.							
					6.		5. Expiration date
l					model #		
1	6. Relevant testeriaboratory data, in	•			catalog #		7. If implanted, give date (mo/duj/y)
		RECE		ן מ	serial #		
		ILCL	_ 1 V L	-	lot #		8. If explanted, give date
		nu 1	0 2001				(makinyiyri
					other # 3. Device avallable for evalu	ation?	tin CDA)
		MEDWAT	CHU	10	yes no	returned to manufact	Turér on
		17122			10. Concomitant medical pro	oducts and thirty ontes (e	nonterior (markey)n
L						306 - 1	·
	Other relevant history, including race, pregnancy, smoking and alco						
		•	•	·	E. Reporter (see c	onfidentality enclin	a on back)
					1. Name, address & phone		TOTT Date N
Į					\$c .		
- 1		•					
				[
				· .	2. Hesith professional? 3.	Occupation	4. Also reported to
L						-seaberron	manufacturer
	Mail to: MEDW	ATCH <i>o</i> i chors L ane	FAX to: 1-800-FD	A-0175	yes no	Manufacilia de la compación de	user facility
		lie, MD 20852-9787			 If you do NOT want your the manufacturer, place 	en "X" in this box.	distributor distributor

FDA Form 3500 (4/03)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

146884

CERT# 0794 7822

MedWatch

The FDA Medical Products Reporting Program

Merck Human Health Division

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

NO ATTACHMENT

Page 1 8 0 8 3 8 4 8 6

Merck Facsimile of FDA Form 3500A Approved by FDA (10/21/93)

Mfr report #	WAES 01062374	_
UF/Dist report #		
	FDA Use On	ΗŅ

A. Patient information	C. Suspect medication(s)
1 Patient identifier 2. Age at time 3. Sex 4. Weight of event:	Name (give labeled strength & mft/labeler, if known) # 1 TAB VIOXX 25 mg
Date of	Jnk #2 aspirin 81 mg
in contidence Birth:	2. Dose, frequency & route used 3. Therapy dates (from/to) (.f unknown, give duration)
B. Adverse event or product problem	#1 25 mg/DAILY/PO #1 03/16/01 - 06/25/01
Adverse event and / or Product problem (e.g., defects/matture	#2 81 mg/DA(LY/PO #2 Unk - 06/25/01
2. Outcomes attributed to adverse event (cneck all that apply) disability	4 Diagnosis for use (indication) S.Event abated after use stopped or dose
death congenital anomaly	reduced. # 1 arthritis pain yes no N/A unk
(mo/day/yr) required intervention to p permanent impairment/de	gevent #2 Unknown #1 X
X hospitalization-initial or prolonged X other: important medica	6. Lot # (if known) 7 Exp gate (if known) #2 X
3. Date of event 06/24/01 4. Date of this report 07/17/0	8. Event reappeared offer reinfroduction.
;morday/yr) (morday/yr) 5 Describe event or problem	9 NDC # - for product problems only (if known)
This is in follow-up to report(s) previously submitte $7/6,91$	Unknown #2 \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
Information has been received from a physician and h.	10. Concomitant medical products and therapy dates (excluden treatment of event)
office nurse concerning a debilitated 30 year old ma.	le KEFLEX Unk -Unk atenolol Unk -Unk
concusion, pneumonia, and no past medical history of gastrointestinal complaints who on 16-MAR-2001, was	
placed on therapy with rofecoxib, 25 mg tablet	G. All manufacturers
(previously reported as 12.5 mg by the physician), or day for the treatment of arthritis pain in his should	
Concomitant therapy included aspirin, 81 mg daily (previously reported as 325 mg daily by the physician	610)397-2416
(duration and indication not reported) (secondary	3. Report source
suspect). Other concomitant therapy included atenclosephalexin (KEFLEX) . On 24-JUN-2001, the patient	
developed a severe gastrointestinal (GI) bleed second to a duodenal ulcer and was hospitalized. On 25-JUN-	dary P.O. Box 4
therapy with rofecoxib and aspirin was discontinued.	2001. The West Point, PA 19486-0004 study
GI bleed required four units of blood. The patient subsequently completely recovered and after four days	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
	X realih
(Continued on Additional Page)	4. Date received by manufacturer (mo/daylyr) (07/10/0] (AINDA # 21042 user lacility
6. Relevant tests/laporatory data, including dates	IND * Company
Unknown	distributor
	pre-1938 yes other
	5-day X 15-day product yes
	10-day periodic 9. Mfr. report number
	initial X Follow-uc# 1 WAES 01062374
	Adverse event term(s) HEMORRHAGIC DUODENAL ULCER
 Other relevant history, including preexisting medical conditions (e.g., altergies.race.pregnancy, smoking and alcohol use, hepatic/renal dystunction, etc.) 	
CONCURRENT CONDITIONS: contact dermatitis; contusion	E. Initial reporter
depility; pneumonia	1. Name, address & phone #
	AVENUE
	DSS
	11 - 1000
	A 0 6-
	2. Health professional? 3. Occupation 4. Inflat reporter also
Submission of a report does not constitute an admission tha	tt X YES NO M.D. sent report to FDA.

B. Adverse event or product problem

5. Describe event or problem

discharged back to the nursing home. According to the nurse, the GI bleed was thought to be related to therapy with rofecoxib and aspirin.

The GI bleed secondary to a duodenal ulcer was considered to be immediately life threatening and an other important medical event. No further information is available.

11. 3 0 Men



CERT# 0794 7822 MedWatch

The FDA Medical Products Reporting Program

Merck Human Health Division

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

NO ATTACHMENT

Merck Facsimile of FDA Form 3500A Approved by FDA [10/21/93]

Mfr report #	WAES 01052780		
UF/Dist report #			
	FDA Use Oni		

				508	3334;	38	L				···
A. Patient in	nformation				spect m		tion(s)				
1. Patient :dentifier	2. Age at time of event:	3. Sex	4. Weight	1. Name (give	labeled strengti	th & mir/labe	eler, :f known)				
	or 63 year	rs Female	114 lbs		VIOXX 50 m						
	Date of	X Male	114105	#2 IAB	aspirin 325 i	mg					
in confidence	Birth:			2 Dose, trequ	ency & route us	sea	3. Therapy	dates (from/t	o) (if unkno	wn, give	duration)
	event or pro	oduct problem (e.g.	, defects/malfunctions)	#1 50 m	ng/DAILY/PC)	#1 0	1/14?/01	- 02/14?	/01	
1 X Adverse event 2. Outcomes attributed to)		12 325	mg/DAILY/P	20	- *2	Unk	- 02/16/0	 01	_
(cneck all that apply)		disability		1	or use (indication		1		ated after u		d or dose
death		congenital an	nomaly	"	ated disc, pa	-		reduced.	no	N/A	unk
life-threatenin	vday/yr)		vention to prevent	+2 rhoun	natic fever			* · X	Ü	ñ	
	ŭ	·	npairment/damage	6. Lot # (if kno		Exp date	(il known)	#2			$\overline{\mathbf{x}}$
X hospitalization	n-initial or prolonge		rtant medical	#1		# 1	,,,,,,,		appeared at	tter :eintre	
3 Date of event :mo/dav/yr)	02/13/01 4	Date of this report (mo/day/yr)	07/17/01	#2	[* 2		yes	no	N/A	unk
5 Describe event or proble			. muhmintad an	9. NDC ≠ - for	product problem	ns only (if kr	Jown.	*1		$\overline{\mathbf{X}}$	
unis is in foll 6:5:01	ow-rb to rebox	rt(s) previously	Submitted on		Unkno	wr:		*2			$\overline{\mathbf{x}}$
information has	hear received	d for a direct r	report from	10 Cancomila	ant medical prod	ticle and in	ya, selen yasıa		ment of eve		<u>(A)</u>
the FDA concern	ing a 63 year	old male patien	it with		(INDOMET		e apy sales lex	Unk -t		111)	
		toms who consume smokes one pack									
		er 2000, was pla g tablet, once a									
creatment of a	herniated C4-0	C5 disc. Concomi	tant therapy	G. All	manufa	acture	ers				
		ce daily (durati 13-FEB-2001 the		1. Contact off	fice - name/addr	ess			ł	ne Numbe	
		and dark, black admitted to the		Merck	Human H	lealth D	ivision		<u> </u>	0)397-2	416
approximately 1	4-FEB-2001, as	fter approximate	ly two months	Merck & Co., Inc.			Report source. (check all that apply)				
		scontinued. The er meals and whe		P.O. B	P.O. Box 4				l lo	reign	,,
		4-FEB-2001 revea		West P	West Point, PA 19486-0004				st	udy	
International Normalized Ratio (INR) was 0.95, partial thromboplastin time (PTT) was 27.7, hemoglobin was 16.5,			titerature								
mean corpuscula:	r volume (MCV)) was 102.5, mea	n corpuscular	ATTN:	Worldwid	le Prod	uct Safety	y	cc	onsumer	
	(Continued on Ad	dditional Page)		4. Date receiv	ed by manufact	turer	5.			eaith rofessiona	al .
6. Relevant tests/laborator				(mo/day/yr	07/11/	/01	(A)NDA # 210)42		ser facility	
Refer to Addit	tional Page			6. II IND. proto	cot #		IND #			mpany presentativ	ve
						-	pre 1938	yes	al:	simbuter	
				7 Type of repo	_		OTC L	_ · !	تت ا	her:	
				: I==	X 15-day	[product L	yes	CTU 1	41188	
				10-day	periodic	_ [9. Mfr. repor		0105278)n	
				8. Adverse eve	X Follow-up#			WAES	0103276		
				DUODENAL	. ULCER; E					SIVE	
					TIS; GAST VTESTINAL		STINAL B	LEEDING	;		
				1 1							
7. Other relevant history, inc	Cluding preexisting medi	cal conditions									
•	•	phol use, hepatic/renal dysfu	nction, etc.)	1							
		ol consumption;		E. Initia	al repor	ter					
disease; rheuman		e; gastroesophag oking	eal reliux	1. Name, addre	ss & pnone #					ر العد	
					AVENUE						
						MEDIC	AL CENTE	R		3.5	ļ
											Ì
								117	20	200	
		A		2. Health profes	sional?	3. Occupa	ition		porter also		
	n of a report does	not constitute an adm	nission that	X YES	☐ NO		arm.D.		ort to FDA	X	unk

B. Adverse event or product problem

5. Describe event or problem

hemoglobin (MCH) was 34, platelet count was 326000, and bleeding time was greater than 15 minutes. An esophagogastroduodenoscopy (EGD) was performed which revealed grade 4 esophagitis, duodenal ulcers, and one post-duodenal ulcer. The patient was placed on therapy with unspecified proton pump inhibitors. On 13-FEB-2001 hemoglobin was stable at 11.6 and the patient was discharged from the hospital. The report indicated that the patient was to remain on "life long" therapy with proton pump inhibitors, but indicated that the symptoms abated following discontinuation of refecexib. Aspirin was considered a secondary suspect medication.

Additional information has been received from the pharmacist who originally reported the information concerning the 63 year old, white, male patient. Additional concurrent conditions included chronic obstructive pulmonary disease and concomitant therapy included indomethacin (MSD). The pharmacist clarified that on approximately 14-JAN-2001 the patient was placed on therapy with refecoxib, 50 mg tablet, once daily for the treatment of pain. Aspirin therapy was for the treatment of rheumatic fever. On 14-FEB-2001 the patient presented to the emergency room with red blood in his stool and dark black stools since the day prior. The patient also complained of vomiting dark, bloody chunks on the morning of 14-FEB-2001. Aspirin therapy was discontinued on 16-FEB-2001. Additional follow up was received from a completed questionaire. The source of the bleeding was identified as the grade IV/erosive esopnagitis and the duodenal ulcer. No tests were completed for Helicobacter Pylori.

The reporting pharmacist considered the gastrointestinal bleeding, duodenal alcer, gastrointestinal alcer, and erosive esophagitis to be Other Important Medical Events. Additional information is not expected.

This report was filed with the FDA. The CTU number is 141198.

6. Relevant tests/laboratory data, including dates

DIAGNOSTIC TEST

<u>Tests</u>	Date	Value Unit	Normal Range
esophagogastroduodenoscopy	02/14/01		
Comment: grade 4 esophagitis, duodenal ulc	ers, one post-duoder	nal ulcer	

LABORATORY RESULTS

<u>Tests</u>	<u>Date</u>	Value Unit	Normal Range
APTT	02/14/01	27.7	tionnar Hange
INR	02/14/01	0.95	
nemoglobin	02/14/01	16.5	
platelet count	02/14/01	326000	
bleeding time	02/14/01	>15 min.	
mean corpuscular hemoglobin	02/14/01	34	
mean corpuscular volume	02/14/01	102.5	
hemoglobin	02/18/01	11.6	

DSS

Die 2 C 200



Individual	Safety Re	eport
*3766762-1-0		
3766762-1-6	30-01	

HE FOR MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting nealth professionals of adverse vents and product problems

Form Approved: OMB	No. 0910-0291 Expires:12/31/94
Use Only	See OMB statement on reverse

FDA Use Only	see OMB sistement on rever			
Triage unit	157958			
ì				

atient information		C. Suspect medic	cation(s)	
1. ant identifier 2. Age at time of event:	3. Sex 4. Weight	Name (give labeled strength		
5515 or	_	bs #1 ASA		
In confidence of birth:	male or	#2		
B. Adverse event or product proble		2. Dose, frequency & route u	used 3. Therapy of	lates (if unknown, give duration)
	(e.g., defects/malfunctions	#1 325 00	i increase for the	H ABRUMANS
2. Outcomes attributed to adverse event			·	
C concenited	anomaly	#2 4. Diagnosis for use (indication)	#2	
(molasylyr) required in	lervention to prevent	#1	onj	5. Event abated after use stopped or dose reduced
life-threatening permanent hospitalization – initial or prolonged other:	impairment/damage	- nophylaxis		Last Contraction
		#2 6. Lot # (if known)		apply
Date of event 6/11/0/ this report	6/13/01	#1	7. Exp. date (if known) #1	apply
(mo/daylyr) (mo/daylyr) Describe event or problem	וטוכווש			Event reappeared after reintroduction
·		9. NDC # (for product problems	#2	#1 yes no doesn't
age_ig adr_desc	AD liability and advance	— -	only) ~	арруу
5575 92 YOF presented to ED with CP on exertion, S and brief syncopal episode. Pt seen by LMD or	n 6/8 for DOE. Hab de	or 10. Concomitant medical proc	ducts and therapy dates (
from 10.2 (5/19) to 7.9. Pt developed black sto denied NA/BRBPR/abd pain. On adm. Hob=5.	ol a few days PTA. Pt 9. VS: BP 92/37.	MEROPICIES	leurscpuzie.	subsection and exemity .
HR=110, stool= heme (+) and black. Pt denies NSAID (aspirin) use for thrombus prophylaxis.	ETOH use but (+)	Kuosenidi	•	
secondary to GI bleed and probable MI second	ary to ischemia. Pt to	lisinopul		
have endoscopy. ASA held. Pt given IVF and lavage (-). On 6/13, pt given 2 additional units	PRBCs. stool no longe	isosorbide monor		
black, Hgb=10.9. No CP or abd pain. Prelimin diverticulosis.	ary BE revealed sigmo	D. Suspect medica	al device	
		2. Type of device		
		 Manufacturer name & addre 	\$S	4. Operator of device
Ì		·		health professional
ade id			~=	lay user/patient
		II KE	CEIVED	other:
		6. JU	L 3 0 2001	5. Expiration date
Relevant tests/laboratory data, including dates		model#		
	•	catalog #	ATOHOLO	7. If implanted, give date (moldaylyr)
		serial #		······································
	26	lot #		8. If explanted, give date
	055	other#		- (moldaylyr)
	20 500	9. Device available for evaluati	00? (De est est	10. 50.0
	Dee 5001	yes no	on? (Do not send	
	30	10. Concomitant medical produ		
Other relevant history, including preexisting medical condit	ions (a n. allemins		1,	and a contient of event)
race, pregnancy, smoking and alcohol use, hepatic/renal dysfun	ction, etc.)			
PMH: CABG, CHF, HTN	1	E. Reporter (see con	fidantiality as-4:	
BLhipreplacement		1. Name, address & phone #		
BL hip replacement GEAD	i	Hospital Hospital	, Ph	armD
	- 1		harmacy Services	
Alleyies = PCN	1	Stre	cet desired	
CTV/147958]	2. Health professional? 3. Oc		
11.11.			i i	4. Also reported to
5600 Fishers Lane 1-8	(to: 00-FDA-0178		armacist	manufacturer
HOCKVINE, MD 20852-9787		 If you do NOT want your ider the manufacturer, place an " 	X " in this box.	user facility distributor
vm 3500 (6/93) Submission of a report does not con-	etitudo on odminain-	Ab - a		



DLUNTARY reporting h professionals of adverse s and product problems

Form Approved OMB Nc. 0910-0291 Expires: 04/30/03 See OMB statement on reverse

FDA Use Only

Triage unit sequence #	148008	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Internet Submission - Page 1

				<u> </u>			
A. Patient information		C. Sus	spect medi	ication(:	s)		
1ºPatient identifier 2. Age at time	3. Sex 4. Weight	1 Name	(Product Name)		eled Strength) /	(Mfr/Labeler)	
of event:	_	#1 asa	(i roccon riame)			/ (Mil/Labeler)	
or —	female lbs	#1		1 10	PIRIN	/	
Date	male or	40		1		7	— <i>!</i>
In confidence of birth:	kgs kgs	#2		/		<u>/</u>	
B. Adverse event or product probler	n	2. Dose/Fre	equency/Route u	sed		les (if unknown, give du	
	e.g., defects/malfunctions)	#1	/ /		#1 From	To (or best e	stimate)
	e.g., deleas/mairunalions)		/ /		"		
Outcomes attributed to adverse event (check all that apply) disability		#2	/ /		#2	-	
- Consonital	anomaly	4 Diagnos	is for use (separa	to indications		E Event should stee	
Ueam	,	F	ia ibi dae (sepaia	ate murcations	with commas)	Event abated afte stopped or dose r	
Man share share in a	tervention to prevent impairment/damage	#1					
	· •	#2				#1yes no 💆	doesn't apply
nospitalization – initial or prolonged other		#2				#0 The F	7doesn't
3. Date of 4. Date of		6. Lot # (if I	known)	7. Exp. d	late (if known)	#2yes no	doesn't apply
event 03/19/2001 this report	07/28/2001	#1		#1		8. Event reappeared	after
(mm/dd/yyyy) (mm/dd/yyyy)						reintroduction	
5. Describe event or problem		#2		#2		#1 Tives Tino T	∃ dosenh ⊟
GI bleed	ł	9. NDC # (f	or product probler	ns only)		#1 yes no	doesn't apply
	ı	· 1	· _ ·	- "		#2 yes no	doesn't
		10.0	-144				
		IV. Concor	nitant medical pr	roducts and	therapy dates (e	exclude treatment of ever	ent)
		1					- 1
		1					
		<u></u>					- 1
		D. Sus	spect medi	cal devi	ice		
		1. Brand na					
		2. Type of c	device				
		3. Manufact	turer name & ado	dress		4. Operator of dev	rice
		1				realth profe	
	1						- 1
	i					lay user/pat	ent
	i	· I	DE	ヘニハ		L. cther:	
	1		コロ	יובוט	VED		
		· I					
		6.		L 3 0	2001	5. Expiration date	, [
	ļ.	1	50	_ 0 0	200.	(mm/cd/yyyy)	
6 Delevent to the last to the		model #		7 7 7 ^ 1	TH		
6. Relevant tests/laboratory data, including dates		catalog #	M+1)V	VA I U	HUIU	7. If implanted, gi	ve date
hct = 22 hgb = 6.8		Catalog #	·	11.11.9.		(mm/dc/yyyy)	1
	į.	serial #					
						8. If explanted, gi	
		lot #				(mm/cd/yyyy)	ve date
		other#				}	1
					<u>_</u>	166	
	ľ		ailable for evalu	ation?	(Do not serio	evide FDA)	1
		∟ yes	no	retu	rned to manufactu	urer on	
		10. Concorn	Itant medical pro	oducts and	therapy dails te	coulde treat heat of ever	<u>////</u>
			,			COD COM COMMONICO CYC	"
7. Other relevant history, including preexisting medical con	ditions						l
(e.g., allergies, race, pregnancy, smoking and alcohol use, hepat	tic/renal dysfunction, etc.)	1					l
asa po 10/day x many years							
		E. Rep	orter (see c	onfidenti	ality section	on back)	
		1. Name			ne#		
YY XY	′≽ .			L.,			
MEDW	ATTITUTE	7	t Hospital;			Nue -	
, ATTIAN	41(.)	Pharmacy	nospical;			Ave.	,
	14	- macy	• .	_			_
م د الله م	100.	United S	- tates				╼
THERROR JUL 30	2001	2. Health pro		3. Occupa	ation	4. Also reported to	
<u> </u>		yes	- · · · · ·		h Professional	(3)	i i
Mail to: MEDWATCH	or FAX to:					manufacture	
5600 m and	130-EDA-0178		not want your ide			user facility	- 1
Rockvi Metable 2018	V P I	the manuf	facturer, place ar	1 "X" in this	box.	distributor	1



THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

OLUNTARY reporting alth professionals of adverse rests and product problems

Internet Submission - Page 1

Form Approved OMB No. 0910-0291 Expires: 84/30/03
See OMB statement on reverse
FDA Use Only
Triage unit

Triage unit sequence #	1	4801	//
		· -	

A. Patient information		C. Suspect medication(s	
Patient identifier 2. Age at time	3. Sex 4. Weight	1. Name (Product Name) (Label	ed Strength) (Mfr/Labeler)
of event:	[] female lbs	#1 excedrin	/
Pale	or		/
In confidence of birth:	kgs	#2 / 2. Dose/Frequency/Route used	Therapy dates (if unknown, give duration)
B. Adverse event or product pr	oblem	Inrn I	From To (or best estimate)
1. Adverse event and/or Product pr	oble m (e.g., defects/malfunctions)	#1 / BT 1	#1
2. Outcomes attributed to adverse event	sability	#2 / /	#2
(Check all triat apply)	ngenital anomaly	4. Diagnosis for use (separate indications w	vith commas) 5. Event abated after use
death	quired intervention to prevent	#1	stopped or dose reduced
	rmanent impairment/damage		#1 yes no doesn't
hospitalization – initial or prolonged ot	ner:	#2	#2 yes no doesn't
3. Date of 4. Date	of		ate (if known)
event 02/24/2001 this	report 07/28/2001	#1 #1	8. Event reappeared after reintroduction
(mm/dd/yyyy) (mm/d	kd/yyyy)	#2 #2	
GI bleed orthostatic hypote	nsion	NDC # (for product problems only)	#1 yes no doesn't
CI DICC CICHOLOGIC MAP			#2 yes no doesn't
	İ	10. Concomitant medical products and	ирріу
		is. Consolition in the process and	(0.0.000 #0.0.000 #0.0.000
		D. Commodenadia Idayi	
		D. Suspect medical devi	ce
		i. Brand name	
		2. Type of device	
		3. Manufacturer name & address	4. Operator of device
			health professional
			lay user/patient
		RECEIV	EU dther:
		 	
		JUL 3 0 2	5. Expiration date
		6.	(mm/dd/yyyy)
		model # - MEDWATCH	- (;+t)
6. Relevant tests/laboratory data, including dates hgb= 6.2 hct= 20		catalog #	7. If implanted, give date
ngb= 6.2 ncc= 20		serial #	
			8 If explanted give date
		lot #	(mm/dd/yyyy)
		other#	_
		9. Device available for evaluation?	(Do not send device t) FSA
		yes no retu	rned to manufacturer on
		10. Concomitant medical products and	therapy dates (exclude treatment of event)
			JUL 9 1 FOOT
7. Other relevant history, including preexisting me			
(e.g., allergies, race, pregnancy, smoking and alcohol	use, hepatic/renal dysfunction, etc.)		
		E. Reporter (see confident	iality section on back)
		1. Name pho	one#
	WW 1000		
ÂA	JUL 3 0 2001	Hospital;	Ave.
₹ V J	ELWATC'H	Pharmacy	,
), Herrina (1997)	United States	
CTV148011 .	JUL 3 n onni	2. Health professional? 3. Occup	ation 4. Also reported to
		yes no Other Heal	th Professional manufacturer
Mail to: MEDWATCH	or FAX to:	5. If you do not want your identity disclo	osed to user facility
5600 Fish 73 Rockville and	1-800-FDA-0178	the manufacturer, place an "X" in this	



VOLUNTARY reporting by health professionals of adverse events and product problems

Internet Submission - Page 1

Form Approved OMB No. 0910-0291 Expires: 04/30/

sequence # 1700/6

A. Patient information	C. Suspect medication(s)
1. Patient identifier 2. Age at time 3. Sex 4. Weight	Name (Product Name) (Labeled Strength) (Mfr/Labeler)
of event:	#1 asa / ASPIRIN /
Or Or	
In confidence of birth: male 64.1 kgs	#2 vioxx
	Dose/Frequency/Route used 3. Therapy dates (if unknown, give duration)
B. Adverse event or product problem	#1 81 mg /qd /Orai #1 From To (or best estimate)
1. Adverse event and/or Product problem (e.g., defects/malfunctions)	
2. Outcomes attributed to adverse event disability	#2 50 mg /qd /Orai #2 -
Concenitel anomaly	4. Diagnosis for use (separate indications with commas) 5. Event abated after use
death required intervention to prevent	#1 1995 had a head CT due to stopped or dose reduced
life-threatening permanent impairment/damage	dizzines?
hospitalization – initial or prolonged other:	#1 yes no ✓ doesn't apply
	6. Lot # (if known) 7. Exp. date (if known) #2 yes no doesn't apply
3. Date of 4. Date of	
event 04/16/2001 this report 07/29/2001 (mm/dd/yyyy)	#1 8. Event reappeared after reintroduction
5. Describe event or problem	#2
GI bleed 5-6 dark stools	9. NDC # (for product problems only) #1 yes no doesn't apply
	#2 yes no doesn't
	10. Concomitant medical products and therapy dates (exclude treatment of event)
	D. Suspect medical device
	1. Brand name
	i. Diana hame
	2. Type of device
	3. Manufacturer name & address 4. Operator of device
	health professional
	☐ lay user/patient
	T other:
	DECEIVED " ""
	RECEIVED
	5 Expiration date
	6. JUL 3 0 2001 (mm/dd/yyyri
	model #
6. Relevant tests/laboratory data, including dates	7. If implanted, give date
H/H 9.1/27 BRB in stools	catalog # MEDWA + UT U (mm/dd/yyyy)
	serial #
	8. If explanted, give date
	lot # (mm/cd/yyyy)
	other#
	9. Device available for evaluation? (Do not send device (FDA)
	yes no returned to manufacture 5
	(mm/dd/yyyy)
	10. Concomitant medical products and therapy dates (exclude treatment of event)
7. Other relevant history, including preexisting medical conditions	JUL 3 1 2001
(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)	
MENIVA	E. Reporter (see confidentiality section on back)
TOWATY L	1. Name phone#
JUL 3 0 2001	
111 200	Hospital, Ave.
30 200i	Pharmacy
/w Parl DET	United States
CTV148016 RECEIVED	2. Health professional? 3. Occupation 4. Also reported to
Mail to: MEDWATCH or FAX to	yes no Other Health Professional manufacturer
5600 Fishers Lane 1-800-FDA-0178	5. If you do not want your identity disclosed to user facility
Rockville, MD 20852-9787	the manufacturer, place an "X" in this box.



/OLUNTARY reporting alth professionals of adverse nts and product problems

Internet Submission - Page 1

THE

Form Approved: OMB No. 0910-0291 Expires: 04/30/03 See OMB statement on reverse

200

riage unk	1	48201
sequence #		10000

THE FOR MEDICAL PRODUCTS REPORTE					
A. Patient information		C. Suspect m	edication(s)	
Patient identifier 2. Age at time	3. Sex 4. Weight	1. Name (Product Na	me) (Lat	oeled Strength)	(Mfr/Labeler)
of event:	femalelbs	ibuprofen #1	/		/
Date	or	asa			1
In confidence of birth:	male kgs	#2 asa	/		/
in confidence		2. Dose/Frequency/Ro	ute used	1	tes (if unknown, give duration)
B. Adverse event or produc		#1 /	/	#1	To (or best estimate)
	duct problem (e.g., defects/malfunctions)	/,	',	l	
Outcomes attributed to adverse event (check all that apply)	disability	#2 /	/	#2	
• • • • • • • • • • • • • • • • • • • •	congenital anomaly	4. Diagnosis for use (s	separate indications	with commas)	5. Event abated after use
death(mm/dd/yyyy)	required intervention to prevent	#1 chronic lower	back pain		stopped or dose reduced
life-threatening	permanent impairment/damage				#1 yes no doesn't
hospitalization – initial or prolonged	other:	#2			
		6. Lot # (if known)	7. Exp.	date (if known)	#2 yes no doesn't
	4. Date of this report 08/01/2001	#1	#1		8. Event reappeared after
event 06/29/2001 (mm/dd/yyyy)	(mm/dd/yyyy)				reintroduction
5. Describe event or problem		#2	#2		#1 [] yes [] no [] doesn't
GI bleed, dizziness ibu	uprofen 6-8 tabs/	9. NDC # (for product p	roblems only)		
day asa 3/day		-	-		#2 yes no doesn't
		10. Concomitant medi	ical products an	d therapy dates (exclude treatment of event)
					D89
					Atte also
					AUG 0 3
		D. Suspect m	redical de	vice	
		1. Brand name			1
		<u> </u>			
		2. Type of device			
		3. Manufacturer name	& address		4. Operator of device
		S. Wallandotale: Halle			health professional
	ŀ				
		l R	ECEI		lay user/patient
	ŀ	1 1		V匚U	other:
			AUG 03	2001	E Englishing data
		6			5. Expiration date (mm'od/yyyy)
		model # MF	WATC	LITO L	
6. Relevant tests/laboratory data, including	dotos		14171-01	7010	7. If implanted, give date
EGD revealed shallow duor		catalog #			(mm/od/yyyy)
erosis-no acute bleeding		serial#			
Hct=23	ng ngb-0.0	Serial #			8. If explanted, give date
1100-23	i	lot #			(mr/dd/yyyy)
					1
		other #		45	- d during to EDA)
		9. Device available fo		•	nd device to FDA)
		│	no l r	eturned to manufa	(mm/dd/yyyy)
}		10. Concomitant med	ical products ar	nd therapy dates (exclude trealment of event)
ľ					
7. Other relevant history, including preexis	sting medical conditions				
(e.g., allergies, race, pregnancy, smoking and	alcohol use, hepatic/renal dysfunction, etc.)				
some ETOH use	MEDIXMIX	E. Reporter (see confide	ntiality section	n on back)
	VICLIVVAIC	1. Name		hone#	
Į					
ĺ	AUG D 2 2004	Hospi	tal	Pharmacy	
	AUG 0 2 2001	Ave.		nai macy	,
}	į				
		United States			
CT1/148290	RECEIVE	2. Health professiona	1? 3. Occ	upation	4. Also reported to
U LI LABOUR	VLL	yes 🗌	no Other He	alth Profession	al manufacturer
Mail to: MEDWA	TCH or FAX to:	5. If you do not want	vour identity dis	erlosed to	user facility
5600 Fish	hers Lane 1-800-FDA-0178	the manufacturer,			distributor
Rockville	e, MD 20852-9787		,		

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting realth professionals of adverse vents and product problems

Internet Submission - Page 1



FDA Use Only

Triage unit

A. Patient information	C. Suspect medication(s)	
Patient identifier 2 Age at time 3. Sex 4 Weight	1 Name (Product Name) (Labeled Strength)	(Mfr/Labeler)
of event: 68 Years	#1 Flavix /70 mg /	
or	Aspirin /300 mg	
In confidence of birth: kgs	#2 /	s (if unknown, give duration)
B. Adverse event or product problem	From	To (or best estimate)
1	#1 75 mg /daily /Orat #1 07/06/20	01 = 07/13/2001
Addison the second seco	#2 325 /daily /orat #2 07/06/20	01 - 07/13/2001
2 Dutcomes attributed to adverse event (check all that apply) disability	"Z mcg /	Event abated after use
congenital aromaly	4. Diagnosis for use (separate indications with commas) #1 status post cardiac stent	stopped or dose reduced
death required intervention to prevent	olacement	#1 yes no doesn't
✓ life threatening permanent impairment/damage	"coronary artery disease	
✓ hospitalization - initial or prolonged other other	6 Lot # (if known) 7 Exp date (if known)	12 yes no lapply
3 Date of 4. Date of	1 ·	8. Event reappeared after
event 07/13/2001 this report 08/06/2001	#1	reintroduction
(mm/cd/yyyy) 5 Describe event or problem	#2 #2	#1 yes no doesn't
Patient underwent a cardiac angioplasty	9. NDC # (for product problems only)	
with stent placement on at a local		#2 yes no doesn't
hospital within the previous week. He	10. Concomitant medical products and therapy dates (ex	colucte treatment of event)
was doing well initially, however, during	Tiazac 240 mg gd, Claritin 10	mg qd
his daily walk today, he felt very weak	Precose 100 mg TID, Atended 1	00 mg QD,
and had difficutly getting home. He felt	Diovan 80 mg qd, Actose 20mg Q	D,
light-headed & dizzy. He was brought into the Emergency room where he was	Ranitidine 150m	
found to have a blood pressure of 122/41		
and pulse of 56. He was also noted to	D. Suspect medical device	
have melancetic stools. The patient was	1. Brand name	
admitted for further evaluation of his	2 Type of device	
apparent Glabieeding and anema.	2 Type of device	
	3. Manufacturer name & address	4. Operator of device
		health professional
		lay user/patient
		other:
	==OCN/ED	Expiration date (#m/dd/yyyy)
	RECEIVED	
	model #	7. If implanted, give date
6 Relevant tests/laboratory data, including dates	catalog # AUG 0 7 2001	(c mischyyyy)
Hgb = 4.5 -7/13/01=	HOU!	
	serial # MEDWATCH CTU	E. If explanted, give date
	lot #	(mm/dd/syyy)
DSS 1	other#	
		d device to FDA)
AUG 0 7 2001		turer on
HOU 0 1 2001		
	10. Concomitant medical products and therapy dates is	Acidde deadlicit of every
	i	
 Other relevant history, including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) 		
NIID, hypertension, chronic back pain,	E. Reporter (see confidentiality section	n on back)
history of orthopedic surgeries on both		
lankles.		
AUG 0 7 2001	PharmD	
MILINX/ATO	Health System Pharmagy	
Allo	United States	L Alexandra da
AUG U 7 2001	2. Health professional? 3. Occupation	Also reported to
	yes no Pharmacist	manufacturer
Mail to: MED WATCH or FAX to:	5. If you do not want your identity disclosed to	: ✓ user facility
5600 PM are 1-800-FDA-0178 Rockville MU 2802-9187	the manufacturer, place an "X" in this box.	distributor
FDA Form 3500 Submission of a report does not constitute an admiss	ion that medical personnel or the product caused or o	ontributed to the event.
FDA Form 3500 Submission of a report does not constitute an admiss	ion piet incured personner of the product and product	

"MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems Internet Submission - Page 5

C10. Concomitant medical products and therapy dates continued

g BID, Lasix 40mg QD, Glyburide 5 mg BID

D10. Concomitant medical products and therapy dates continued

DSS

AUG 0 7 2001

Mail to: MEDWATCH

or FAX to:

5600 Fishers Lane Rockville, MD 20852-9787

1-800-FDA-0178

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

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